IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF WEST VIRGINIA AT CLARKSBURG

WYETH, Plaintiff,)))	
)	
V.)	Civil Action No. 1:07 CV91
)	(Judge Irene M. Keeley)
MYLAN PHARMACEUTICALS, INC.,)	
)	
Defendant.)	
)	

PLAINTIFF WYETH'S BIOGRAPHICAL SKETCHES OF PROPOSED EXPERT WITNESSES

Pursuant to the Court's Scheduling Order of November 13, 2007 [D.E. 39], Plaintiff Wyeth submits herewith biographical sketches of the experts it intends to call as witnesses at trial.

Wyeth's Proposed Expert Witnesses

Wyeth lists hereunder the name and general specialties of the experts it proposes to call as witnesses at trial. The listed experts' specialties are also set forth in detail in their expert reports that have been served in this case, and in the attached curriculum vitae.

Dr. Henry Grabowski (live)
 Department of Economics
 Duke University
 213 Social Sciences
 Box 90097
 Durham, North Carolina 27708-0097

Professor Henry G. Grabowski, Ph.D., is an expert in the field of the economics of the pharmaceutical and health industries. He has over 40 years of experience in the study of

economics, much of it in the pharmaceutical and health care industries. Dr. Grabowski holds a B.S. in Engineering Physics from Lehigh University, and both master's and doctorate degrees in Economics from Princeton University. After receiving his Ph.D., Dr. Grabowski held positions at Yale University as an Assistant Professor of Economics and as a Research Associate at the National Bureau of Economic Research. In 1972, Dr. Grabowski became an Associate Professor of Economics at Duke University. In 1976, he became a Full Professor of Economics at Duke University, and in 2009, he became Professor Emeritus there. From 1983 to present, Dr. Grabowski has also served as the Director of Duke University's Program in Pharmaceuticals and Health Economics, that focuses on the study of economics of these industries. Over his career he has taught a graduate level course on economic and policy issues facing the pharmaceutical industry.

Dr. Grabowski also served on the Board of Directors for Triangle Pharmaceuticals, Inc. prior to its acquisition by Gilead Pharmaceuticals in 2003. Triangle Pharmaceuticals was a development stage company focusing on antiviral therapies. Dr. Grabowski has also consulted with numerous pharmaceutical companies during his career. Dr. Grabowski has also been an advisor and consultant to a number of government agencies including the National Academy of Sciences, the Federal Trade Commission, the General Accounting Office, and the Office of Technology Assessment. Dr. Grabowski has also served as a Research Fellow at the International Institute of Management in Berlin, Germany, as a Visiting Scholar at the Health Care Financing Administration from 1979 to 1980, and for the Office of Health Economics in London, and the Centre for Medicines Research in London.

Dr. Grabowski's academic and research specialties include the pharmaceutical industry and health economics, the economics of innovation, government regulation of business, and

industrial organization. Dr. Grabowski has authored numerous books, articles and papers on economic issues facing the pharmaceutical industry. He has also testified before several Congressional committees regarding such issues as effective patent life for pharmaceuticals, competition by generic pharmaceutical companies, health care reform legislation during the Clinton Administration, and more recently on a possible abbreviated regulatory system for biologics. Under a series of grants from the National Science Foundation, Dr. Grabowski examined the economics of research and development (R&D) of the pharmaceutical industry, and the effect of government policies on innovation in the industry.

Dr. Grabowski is also an Adjunct Scholar and Advisory Board member for Health Policy Research at the American Enterprise Institute for Public Policy Research. He is on the Board of Scientific Advisors for the American Council of Science and Health. Dr. Grabowski is also an Associate Editor for The Quarterly Review of Economics and Finance, and previously served as an Associate Editor for The Journal of Research in Pharmaceutical Economics.

A more detailed description of Dr. Grabowski's professional experience appears in his CV, which is attached as Exhibit A.

Dr. Eric Hollander (live)
 Neuropharmacology Services, LLC, and Institute of Clinical Neurosciences
 300 Central Park West
 Suite 1C
 New York, New York 10024

Dr. Eric Hollander, a practicing psychiatrist and former professor of psychiatry, has over 20 years of experience in the fields of psychiatry and psychopharmacology, including depression and anxiety, the treatment of depression and anxiety, and the use and prescription of pharmaceutical antidepressants and anxiolytics. Dr. Hollander received a Bachelors of Arts degree in psychology from Brandeis University in 1978, and a medical degree from the State

University of New York, Downstate Medical College in 1982. He was a resident in internal medicine and psychiatry at Mount Sinai from 1982-1986, was Chief Resident in Psychiatry Research during his last year of residency, completed a fellowship in psychopharmacology and anxiety disorders at Columbia University College of Physicians and Surgeons and New York State Psychiatric Institute from 1986-1988, and has been a practicing psychiatrist since he completed his residency in 1986. In his clinical work, Dr. Hollander has personally treated over a thousand patients suffering from psychiatric disorders including depression and anxiety. In his teaching, he has taught courses on the diagnosis, psychopharmacology and neurobiology of anxiety, mood and compulsive/impulsive disorders as well as on autism and developmental disorders. He is currently a Research Attending Psychiatrist at Montefiore Medical Center University Hospital for Albert Einstein College of Medicine in New York and the Director of the Institute of Clinical Neuroscience and Director of Neuropharmacology Services in New York, New York.

Dr. Hollander began his teaching career in 1986 as an Instructor of Clinical Psychiatry at Columbia University. He became Assistant Professor at Columbia University in 1988, and Associate Professor in 1992. In 1993 he transitioned to Mount Sinai School of Medicine as an Associate Professor of Psychiatry. Dr. Hollander became a full Professor of Psychiatry in 1996. During his 15 years at Mt. Sinai, Dr. Hollander was the Chairman of Psychiatry, the Director of the Compulsive, Impulsive, and Anxiety Disorder Program, the Director of Clinical Psychopharmacology, the Director of the Seaver Autism Research Center, the Director of Greater New York Autism Center of Excellence at the Mount Sinai School of Medicine, and the Esther and Joseph Klingenstein Professor of Psychiatry. During his tenure at Mt. Sinai, Dr. Hollander had 700 psychiatrists reporting directly or indirectly to him.

Dr. Hollander has extensive experience with the diagnosis and treatment of depression and anxiety disorders and with prescribing practices for antidepressant medications. He has written more than 500 articles on psychiatry and psychopharmacology and has edited or coedited several textbooks related to anxiety disorders. In addition, Dr. Hollander has received numerous awards, including a Distinguished Fellow Award from the American Psychiatric Association, Distinguished Investigator Awards from the National Alliance for Research in Schizophrenia and Depression, and a Research Scientist Development Award from the National Institute of Mental Health.

A more detailed description of Dr. Hollander's professional experience appears in his CV, which is attached as Exhibit B.

3. Dr. James W. McGinity (live)
College of Pharmacy
The University of Texas at Austin
Austin, Texas 78712-1074

Dr. James W. McGinity is a pharmaceutical scientist with over 35 years of practical hands on experience in the fields of pharmaceutical processing and extended release technologies, as well as experience in training those newly becoming skilled in the art of pharmaceutical research and development. Dr. McGinity received a Bachelor of Pharmacy degree from the University of Queensland in 1967, and a Ph.D. in Physical Pharmacy from the University of Iowa in 1972.

After receiving his Ph.D., Dr. McGinity worked as a Research Investigator for E.R. Squibb and Sons, in New Brunswick, New Jersey. While at E.R. Squibb, Dr. McGinity developed formulations for oral, ophthalmic and topical drug products. Dr. McGinity joined the faculty at the School of Pharmacy at Texas Southern University in 1973 as an Associate

Professor of Pharmacy. Dr. McGinity then moved to the College of Pharmacy at the University of Texas in 1976, where he still teaches. In his time at the University of Texas, Dr. McGinity has held the titles of Assistant Professor, Associate Professor, and finally full Professor as of 1985. Dr. McGinity was the Assistant Director and Director of the Drug Dynamics Institute at the College of Pharmacy from September 1979 to August 2008, and the Division Head of Pharmaceutics from 1983 until August 2007. Dr. McGinity has taught numerous graduate and undergraduate courses including Product Development, Advanced Manufacturing Pharmacy, Advanced Pharmaceutical Processes, and Pharmaceutical Dosage Forms.

Dr. McGinity's research interests include preformulation, materials science, tablet technology, film coating and pellet technologies, pharmaceutical processing, and the design of extended release dosage forms. Dr. McGinity has published over 160 articles in peer-reviewed journals, over 25 book chapters, has been named as an inventor on 23 US patents, and has delivered over 300 presentations at scientific meetings. The majority of Dr. McGinity's publications and presentations focus on oral extended release formulations. Dr. McGinity also serves on the editorial board of 9 peer-reviewed journals and is the US editor for the European Journal of Pharmaceutics and Biopharmaceutics and the co-editor of the textbook Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms.

In addition to his work in academia, Dr. McGinity served for ten years as the Chief Executive Officer of PharmaForm, L.L.C., a fee-for-service and drug delivery research and development company. Dr. McGinity's tenure as CEO of PharmaForm ended when the company was purchased by a public Canadian Pharmaceutical Company in January 2007, but Dr. McGinity has continued to consult for the company since that time. In connection with his work for Evonik, a supplier of acrylic polymers used primarily in film coatings for

pharmaceutical products, he has provided information on the properties and applications of Evonik's products to pharmaceutical scientists in both academia and the pharmaceutical industry. Throughout his career, Dr. McGinity has also served as a pharmaceutical formulation consultant to not only numerous innovator and generic companies, but to the FDA as well.

Dr. McGinity is a frequent lecturer at International Symposia and Conferences. He is also the recipient of many honors and awards, and is currently scheduled to receive the 2009 Distinguished Alumnus Award from the College of Pharmacy from the University of Iowa on October 10, 2009.

A more detailed description of Dr. McGinity's professional experience appears in his CV, which is attached as Exhibit C.

4. Dr. Ronald J. Sawchuk (live)
Department of Pharmaceutics
College of Pharmacy
Room 9-143 Weaver-Densford Hall
University of Minnesota
308 Harvard Street, N.E.
Minneapolis, Minnesota 55455

Dr. Ronald A. Sawchuk is an expert in the fields of pharmacokinetics, pharmacodynamics, and biopharmaceutics. He has over 35 years of experience in academia, and has served as a consultant to the pharmaceutical industry for more than 25 years. Dr. Sawchuk has both a Bachelor and Master's of Science in Pharmacy degree from the University of Toronto, and a Ph.D. in Pharmaceutical Chemistry with a focus in Pharmacokinetics from the University of California, San Francisco. Dr. Sawchuk's research currently focuses on neuropharmaceutics and the delivery of drugs to the central nervous system.

Dr. Sawchuk began his teaching career as an Instructor in Pharmaceutics at the University of Minnesota in 1971. He became an Assistant Professor of Pharmaceutics in 1972,

an Associate Professor in 1977, and a Full Professor in 1983. Dr. Sawchuk has served as Associate Director and Director of the Clinical Pharmacokinetics Laboratory at the College of Pharmacy at the University of Minnesota. He has also served as the Director of Graduate Studies in Pharmaceutics and the Head of the Department of Pharmaceutics at the University of Minnesota. Dr. Sawchuk currently holds the titles of Morse Alumni Distinguished Teaching Professor of Pharmacokinetics, and Director of the Bioanalytic and Pharmacokinetic Services Laboratory, at the University of Minnesota College of Pharmacy. He has taught classes in pharmacokinetics, advanced pharmacokinetics, basic pharmacokinetic modeling, and advanced neuropharmaceutics.

Dr. Sawchuk is currently on the editorial board of *Xenobiotica* and the editorial advisory boards of the *AAPS Journal* and the *Saudi Pharmaceutical Journal*, and has recently served for more than ten years on the editorial board of the *Journal of Pharmaceutical Sciences*. He has written six books/chapters, over 100 peer-reviewed scientific publications, and over 175 abstracts. Dr. Sawchuk is an inventor on a patent for methods and compositions for applying pharmacologic agents to the ear. He is also a frequent invited lecturer at universities, workshops, and pharmaceutical companies, and has served as the co-chair, co-organizer or scientific advisor for numerous symposia.

Dr. Sawchuk was the recipient of the 2007 American Pharmacists Association (APhA)

Research Achievement Award in the Pharmaceutical Sciences, in recognition for his

contributions in the area of basic pharmaceutical sciences and specifically for his work in the

areas of concentration monitoring of antibiotics and in microdialysis pharmacokinetics. His

other honors include the Weaver Medal of Honor, and as a fellow with the American Association

of Pharmaceutical Scientists and the American Association for the Advancement of Science.

In addition to his experience in academia, Dr. Sawchuk has served as a consultant to pharmaceutical companies and/or taught courses at companies such as Sandoz Pharmaceuticals, Novartis AG, Abbott Laboratories, Bristol-Myers Squibb, Schering Plough Corp., Millennium Pharmaceuticals, Gilead Sciences, Boehringer-Ingelheim Pharmaceuticals, Lundbeck Research, Theravance, Inc., Allergan, Inc., Genentech, and the U.S. Patent and Trademark Office.

A more detailed description of Dr.Sawchuk's professional experience appears in his CV, which is attached as Exhibit D.

Dr. Dhiren R. Thakker (live)
 University of North Carolina School of Pharmacy
 Division of Molecular Pharmaceutics
 301 Pharmacy Lane
 Beard Hall, Room #26
 Chapel Hill, North Carolina 27599-7360

Professor Dhiren R. Thakker, Ph.D., is an expert in fields of pharmacokinetics and drug metabolism, including the absorption, metabolism, and distribution of drugs in the body. He has over 35 years of experience in government, private industry, and academia. Dr. Thakker has a B.Pharm from the University of Bombay, a masters degree in pharmaceutical chemistry from Columbia University, and a doctorate degree in biochemistry from the University of Kansas. After receiving his Ph.D., Dr. Thakker held positions at the National Institutes of Health, conducting research in various areas, including research involving drug metabolism. Dr. Thakker later moved to the United States Food and Drug Administration's (FDA) Division of Biochemistry and Biophysics, Center for Drugs and Biologics, where he led a group, had his own research program, and also served as an internal expert to the FDA on the development of biopharmaceuticals.

After several years at the FDA, Dr. Thakker took a position in the Department of Drug Metabolism at Glaxo Inc., where he dealt with issues involving drug absorption, metabolism, excretion, and distribution. Dr. Thakker subsequently became the head of the department in 1990 and Director in 1992. While at Glaxo he had responsibility for supervising over 40 scientists involved in drug discovery and development, including the evaluation of pharmaceutical formulations, such as extended release dosage forms. Dr. Thakker's research at Glaxo also included the impact of efflux transporters on drug absorption, metabolism, and distribution, as well as research in the areas of cytochrome P450 metabolic enzymes.

While working at Glaxo, Dr. Thakker also was an adjunct professor in the Department of Pharmacology, School of Medicine, and Division of Medicinal Chemistry and Natural Products, School of Pharmacy, at the University of North Carolina, Chapel Hill. In 1996 after leaving Glaxo, he was appointed Ferguson Distinguished Professor at the School of Pharmacy, with a joint appointment in the Department of Pharmacology. From 1998 to 2008, he also served as the Associate Dean for Research and Graduate Education and currently serves as the Associate Dean for Economic Development and International Partnerships.

Dr. Thakker's current areas of research include cytochrome P450-mediated drug metabolism, mechanisms of drug absorption across the gastrointestinal epithelium, the interaction of drug metabolizing enzymes and P-glycoprotein efflux transporter, and drug disposition in pediatric populations. He teaches courses in pharmaceutics and drug metabolism to graduate and professional students, and pharmaceutical scientists. Dr. Thakker also consults and lectures on the integration of ADME (absorption, distribution, metabolism, excretion) properties in drug discovery for optimizing clinical drug candidates.

Dr. Thakker also is a Fellow of the American Association of Pharmaceutical Scientists. He has coauthored over 150 articles and numerous textbook chapters in the fields of drug transport mechanisms, drug adsorption, and drug metabolism. He also has served as an editor and currently serves on editorial boards of several peer reviewed journals. Dr. Thakker is an inventor on patents and patent applications in the fields of drug metabolism, absorption enhancers, and screening of drug candidates for metabolic stability.

A more detailed description of Dr. Thakker's professional experience appears in his CV, which is attached as Exhibit E.

6. Dr. Ronald A. Thisted (live)
Department of Health Studies
The University of Chicago
5841 South Maryland Avenue (MC 2007)
Chicago, Illinois 60637

Department of Statistics The University of Chicago 5734 University Avenue Chicago, Illinois 60637

Dr. Thisted is a biostatistician and epidemiologist with over thirty years of experience in the design, execution, and analysis of clinical trials. He has a Bachelors degree in Mathematics and Philosophy from Pomona College, and a Master's and Ph.D. in Statistics from Stanford University.

Dr. Thisted has served on the faculty at the University of Chicago since 1976, when he was appointed Assistant Professor in the Department of Statistics. Beginning in 1999, he has served as Chairman of the Department of Health Studies, which encompasses the fields of biostatistics, epidemiology, and health services research. He also holds joint appointments as a Professor at the University in the Departments of Health Studies, Anesthesia and Critical Care, and Statistics. In addition to his own research, Dr. Thisted supervises graduate students in statistics and health studies, and teaches undergraduate, graduate students, medical students, residents and medical fellows in statistical methods, epidemiology and research design. He also

contributes to an advanced course in pharmacoepidemiology, which relates to monitoring the consequences of drug use in a population, and also includes studying side effects.

Dr. Thisted has been regularly involved in the design and statistical analysis of clinical trials since the late 1970s. In this capacity, he serves as Scientific Director of the Biostatistics Core Facility of the University of Chicago Cancer Research Center, where he provides scientific oversight, guidance and management to Ph.D. and Master's level statisticians in the design and analysis of clinical studies for over 50 on-going collaborations. Dr. Thisted also consults with pharmaceutical and medical device companies seeking regulatory approval to market new products in the U.S. and foreign countries. In conjunction with this work he has had numerous interactions with the FDA including pre-NDA meetings to discuss the types of studies and data analyses that will be conducted to support potential approval of a drug, and discussions of specific issues raised by the FDA during the approval process.

Dr. Thisted has authored or co-authored over 90 original articles in peer-reviewed scientific publications, including The New England Journal of Medicine, The Archives of General Clinical Psychiatry, Journal of the American Medical Association, and Journal of the American Statistical Association. He has authored a book in the field of statistical computation, and contributed over 25 book chapters, comments, reviews and other publications to the statistical literature. Dr. Thisted is an elected fellow of the American Association for the Advancement of Science and the American Statistical Association. He is also a member of the American Public Health Association, the Association for Computing Machinery, the Biometric Society, and the Institute of Mathematical Statistics.

A more detailed description of Dr. Thisted's professional experience appears in his CV, which is attached as Exhibit F.

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This 6th day of October, 2009.

Respectfully submitted,

By: /s/ John Porco

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IN THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF WEST VIRGINIA AT CLARKSBURG

WYETH,	
Plaintiff,	(Judge Irene M. Keeley)
v.)
MYLAN PHARMACEUTICALS, INC.)
Defendant.)))

CERTIFICATE OF SERVICE

I hereby certify that PLAINTIFF WYETH'S BIOGRAPHICAL SKETCHES OF PROPOSED EXPERT WITNESSES was electronically filed with the Clerk of the Court on October 6, 2009, using the CM/ECF system, which will send notification of such filing to the following:

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WYETH, Plaintiff

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Attorneys for Plaintiff

Exhibit A

CV of Dr. Grabowski

VITA

Henry George Grabowski

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Department of Economics

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305 Social Sciences

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Telephone:

grabow@econ.duke.edu

Born:

September 20, 1940 in Scranton, Pennsylvania

Married, three children

Education:

Lehigh University, B.S., Engineering Physics, 1962 Princeton University, M.A., Economics, 1964 Princeton University, Ph.D., Economics, 1967

Professional Career:

University, 1983-

Assistant Professor in Economics Department, Yale University, 1967-1971 Research Associate, National Bureau of Economic Research, 1971-1972 Associate Professor in Economics Department, Duke University, 1972-1976 Professor in Economics Department, Duke University, 1976-Research Fellow, International Institute of Management, Berlin, Germany, 1976 Visiting Scholar, Health Care Financing Administration, Office of Research, Washington, D.C. 1979-1980 Director, Program in Pharmaceuticals and Health Economics, Duke

Professional Organizations and Board Memberships:

Adjunct Scholar and Advisory Board Member for Health Policy Research,
American Enterprise Institute for Public Policy Research
Board of Scientific Advisors, American Council on Science and Health
Associate Editor, The Quarterly Review of Economics and Finance
Associate Editor, Journal of Research in Pharmaceutical Economics

Major Fields of Interest:

Industrial Organization Economics of Innovation Economics Government Regulation of Business Pharmaceutical Industry-Health

Publications

Books and Monographs:

<u>Drug Regulation and Innovation: Empirical Evidence and Policy Options</u>, (American Enterprise Institute for Public Policy Research: Washington, D.C.), 1976.

The Impact of Regulation on Industrial Innovation (with John Vernon) (National Academy of Sciences: Washington, D.C.), 1979.

The Regulation of Pharmaceuticals: Balancing the Benefits and Risks (with John Vernon) (American Enterprise Institute for Public Policy Research: Washington, D.C.), 1983.

<u>Health Reform and Pharmaceutical Innovation</u> (American Enterprise Institute for Public Policy Research: Washington, D.C.), 1994.

The Search for New Vaccines: The Effects of the Vaccines for Children Program, (American Enterprise Institute for Public Policy Research: Washington, D.C.), 1997.

Articles:

"A Graph-Oriented Model for Research Management," (with Oscar Morgenstern and R. W. Shepherd), in M. C. Yovits, D. M. Gilford, E. Staveley, and H. D. Lerner, eds., <u>Research Program Effectiveness</u>, (Gordon and Breach: New York), 1966, pp. 187-216.

"The Determinants and Effects of Industrial Research and Development Expenditures," <u>Journal of Political Economy</u>, Vol. 76, No. 2, March/April, 1968, pp. 292-306; reprinted in K. S. Palda, ed., <u>Readings in Managerial Economics</u>, (Prentice-Hall), 1973; also reprinted in S. Yamey, ed., <u>Economics of Industrial Structure</u>: <u>Selected Readings</u>, (Penguin Modern Economics Series), 1973.

"Industrial Organization: The Role and Contribution of Econometrics," (with Dennis Mueller), American Economic Review, Vol. 60, No. 2, May 1970, pp. 100-104.

"Demand Shifting, Optimal Firm Growth, and Rule-of-Thumb Decision Making," Quarterly Journal of Economics, Vol. 84, May 1970, pp. 217-235.

"Non-Price Competition in the Cigarette Industry: A Comment," (with Dennis Mueller), Antitrust Bulletin, Vol. 40, Winter 1970, pp. 257-292.

"Imitative Advertising in the Cigarette Industry," (with Dennis C. Mueller), <u>The Journal of American and Foreign Antitrust and Trade Regulation</u>, Vol. 16, No. 2, Summer 1971, pp. 257-292.

"Determinants and Distributional Aspects of Enrollment in U.S. Higher Education," (with A. Corazzini and D. Dugan), Journal of Human Resources, Winter 1972, pp. 39-59.

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"Rivalry in Research and Development: An Empirical Study," (with Nevins D. Baxter), Journal of Industrial Economics, Vol. 21, No. 2, July 1973, pp. 209-235.

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"Structural Effects of Regulation on Innovation in the Ethical Drug Industry," (with John Vernon), Chapter 10, in Robert T. Masson and P. David Qualls, eds., <u>Essays on Industrial Organization in Honor of Joe S. Bain</u>, (Ballinger Publishing Company: Cambridge), 1976, pp. 181-205.

"The Effects of Advertising on the Interindustry Distribution of Demand," in Occasional Papers of National Bureau of Economic Research, <u>Explorations in Economic Research</u>, Vol. 3, Winter 1976, pp. 21-75.

"The Effects of Regulatory Policy on the Incentives to Innovate: An International Comparative Analysis," (with John Vernon and Lacy Glenn Thomas), in Emery A. Link and Samuel Mitchell, eds., Impact of Public Policy on Drug Innovation and Pricing, (American University: Washington, D.C.), 1976, pp. 47-93.

"Consumer Protection Regulation in Ethical Drugs," (with John Vernon), <u>American</u> Economic Review, Vol. 67, February 1977, pp. 359-364.

"Estimating the Effects of Regulation on Innovation: An International Comparative Analysis of the Pharmaceutical Industry," (with John M. Vernon and Lacy Glenn Thomas), <u>Journal of Law and Economics</u>, Vol. 21, No. 1, April 1978, pp. 133-163.

"The Effects of Advertising on IntraIndustry Shifts on Demand," in Occasional Papers of National Bureau of Economic Research, Explorations in Economic Research, Vol. 4, No. 5, Fall 1978, pp. 675-701.

"Consumer Product Safety Regulation," (with John M. Vernon), <u>American Economic</u> Review, Vol. 68, May 1978, pp. 284-289.

"Industrial Research and Development, Intangible Capital Stocks, and Firm Profit Rates," (with Dennis Mueller), Bell Journal of Economics, Vol. 9, No. 2, Fall 1978, pp. 328-343.

"New Studies on Market Definition, Concentration, Theory of Supply, Entry and Promotion," (with John M. Vernon), in Robert I. Chien, ed., <u>Issues in Pharmaceutical</u> Economics, (Lexington Books: Lexington, Mass.), 1979, pp. 29-52.

"Regulation of the United States Pharmaceutical Industry: Current Problems and Policy Developments," in George Teeling-Smith, ed., <u>Medicines for the Year 2000</u>, (Office of Health Economics: London, England), 1979, pp. 57-74.

The Effects of Product Quality Regulation on Innovation in the U.S. Pharmaceutical Industry, Final Report for the National Science Foundation Grant PRA 75-19823 (National Technical Information Services, Washington, D.C.), 1979.

"The Impact of Regulation on Innovation," <u>Food Drug Cosmetic Law Journal</u>, Vol. 34, No. 10, October 1979, pp. 555-560.

"Substitution Laws and Innovation in the Pharmaceutical Industry," (with John Vernon), Law and Contemporary Problems, Winter/Spring Issue, 1979, pp. 43-66.

"Regulation and the International Diffusion of Pharmaceuticals," in Robert B. Helms, ed., <u>The International Supply of Medicines</u>, (American Enterprise Institute for Public Policy Research: Washington, D.C.), 1980, pp. 5-36.

"The Determinants of R&D Expenditures," (with John Vernon), in Robert B. Helms, ed., <u>Drugs and Health</u>, (American Enterprise Institute for Public Policy Research: Washington, D.C.), 1981, pp. 3-20.

"Regulation and Industrial Innovation," in <u>Industrial Innovation and Public Policy Options:</u>
<u>Background Papers for a Colloquium</u>, (National Academy Press: Washington, D.C.),
1981, pp. 65-81.

"Auto Safety Regulation: An Analysis of Market Failure," (with Richard J. Arnould), <u>The</u> Bell Journal of Economics, Vol. 12, No. 1, Spring 1981, pp. 27-48.

"Public Policy and Innovation: The Case of Pharmaceuticals," <u>Technovation</u>, Vol. 1, 1982, pp. 157-189.

"A Sensitivity Analysis of Expected Profitability of Pharmaceutical Research and Development," (with John Vernon), <u>Managerial and Decision Economics</u>, Vol. 3, No. 1, March 1982, pp. 36-40.

"Public Policy and Pharmaceutical Innovation," <u>Health Care Financing Review</u>, Vol. 4, No. 1, September 1982, pp. 75-87.

"An Evaluation of the Maximum Allowable Cost Program," (with Jean P. Gagnon), in <u>The Effectiveness of Medicines in Containing Health Care Costs</u>, Proceedings of a Symposium of the National Pharmaceutical Council, Washington, D.C., 1982, pp. 81-113.

"The Pharmaceutical Industry," (with John M. Vernon), in Richard R. Nelson, ed., Government and Technical Progress - A Cross-Industry Analysis, (Pergamon Press: New York), 1982, pp. 283-360.

"Automobile Safety Regulation: A Review of the Evidence," (with Richard J. Arnould), in Richard O. Zerbe, ed., Research in Law and Economics, Vol. 5, 1983, pp. 233-267.

"The Impact of Patent and Regulatory Policies on Drug Innovation," <u>Medical Marketing & Media</u>, Vol. 18, No. 10, October 1983, pp. 42-63.

"A Computer Simulation Model of Pharmaceutical Innovation," (with John Vernon), in Bjorn Lindgren, ed., <u>Pharmaceutical Economics</u>, (Swedish Institute for Health Economics and Liber Forlag: Lund, Sweden), 1984, pp. 159-175.

Studies on Drug Substitution, <u>Patent Policy and Innovation in the Pharmaceutical Industry</u>, Final report to the National Science Foundation available from the National Technical Information Services, Number PB-85-109700, Washington, D.C., 1985.

"Organizational Capital and the Choice between Specialization and Diversification," (with Michael Gort and Robert McGuckin), <u>Managerial and Decision Economics</u>, Vol. 6, No. 1, March 1985, pp. 2-10.

"Economic Aspects of Vaccine Innovation and Manufacturing," (with Lawrence De Brock), Chapter 4, in <u>Vaccine Supply and Innovation</u>, (National Academy Press: Washington, D.C.), 1985, pp. 45-64.

"Longer Patents for Lower Imitation Barriers: The 1984 Drug Act," (with John Vernon), The American Economic Review, Vol. 76, May 1986, pp. 195-198.

"Health Care Cost Containment and Pharmaceutical Innovation," in <u>Proceedings of the Conferences on Health Care and the Elderly</u>, (Washington, D.C.), 1986, pp. 25-28.

"Pioneers, Imitators, and Generics--A Simulation Model of Schumpeterian Competition," (with John Vernon), The Quarterly Journal of Economics, August 1987, pp. 491-525.

"The Health/Economic Benefits of Drug Therapy: Efficacy, Low Risk, Cost Effectiveness, Patient Information and Emancipation," Swiss Pharma, Vol. 9, No. 3a, 1987, pp. 29-31.

"Impact of Patent and Regulatory Policies on Drug Innovation," <u>Proceedings of the Second Annual Shearson Lehman Hutton Conference on Legal and Regulatory Issues Affecting Biotechnology and Health Care</u>, (Shearson Lehman Hutton, Inc.: New York), October 1988, pp. 5-16.

"Medicaid Patients' Access to New Drugs," Health Affairs, Winter 1988, pp. 102-114.

"Price and Availability Tradeoffs of Automobile Insurance Regulation," (with W. Kip Viscusi and William N. Evans), <u>Journal of Risk and Insurance</u>, Vol. LVI, No. 2, June 1989, pp. 275-299.

"An Analysis of U.S. International Competitiveness in Pharmaceuticals," <u>Managerial and Decision Economics</u>, Special Issue, 1989, pp. 27-33.

"Economic Scales and Tests," (with Ronald W. Hansen), in B. Spilker, ed., Quality of Life Assessments in Clinical Trials, (Raven Press, Ltd.: New York), 1990, pp. 61-69.

"Innovation and International Competitiveness in Pharmaceuticals," in Arnold Heertje and Mark Perlman, eds., <u>Evolving Technology and Market Structure: Studies in Schumpeterian Economics</u>, (University of Michigan Press), 1990, pp. 167-185.

"A New Look at the Returns and Risks to Pharmaceutical R&D," (with John Vernon), Management Science, Vol. 36, No. 7, July 1990, pp. 804-821.

"The Changing Economics of Pharmaceutical Research and Development," in Annetine C. Gelijns and Ethan A. Halm, eds., <u>The Changing Economics of Medical Technology</u>, (National Academy Press: Washington, D.C.), 1991, pp. 35-52.

"Product Liability in the Pharmaceuticals: Comments on Chapters Eight and Nine," in Peter W. Huber and Robert E. Litan, eds., <u>The Liability Maze: The Impact of Liability Law on Safety and Innovation</u>, (Brookings Institution: Washington, D.C.), 1991, pp. 360-366.

"The Cost of Innovation in the Pharmaceutical Industry," (with Joseph DiMasi, Ronald Hansen and Louis Lasagna), Journal of Health Economics, Volume 10, 1991, pp. 107-142.

"Pharmaceutical Research and Development: Returns and Risk," Sixth Annual Centre for Medicines Research Lecture 1991, Centre for Medicines Research, Surrey, England, 1991.

"The Effect of Medicaid Formularies on the Availability of New Drugs," (with Stuart O. Schweitzer and S. Renee Shiota), <u>PharmacoEconomics</u>, Vol. 1 (Suppl. 1), 1992, pp. 32-40.

"The Costs and Returns to Pharmaceutical Research and Development," <u>Rivista Internazionale di Scienze sociali</u>, (International Social Studies Review), September 1992, pp. 347-358.

"Brand Loyalty, Entry and Price Competition in Pharmaceuticals After the 1984 Drug Act," (with John M. Vernon), <u>Journal of Law and Economics</u>, Vol. 35, No. 2, October 1992, pp. 331-350.

"Pharmaceuticals and Health Care Costs," <u>Proceedings of the First International Health</u> Care Forum, Health Care Policy and the Pharmaceutical Industry, Gotemba, Japan, 1993.

"Health Reform and Pharmaceutical Innovation," <u>Seton Hall Law Review</u>, Vol. 24, No. 3, 1994, pp. 1221-1259.

"Innovation and Structural Change in Pharmaceuticals and Biotechnology," (with John Vernon), <u>Industrial and Corporate Change</u>, Vol. 3, No. 2, 1994, pp. 435-449.

"Returns to R&D on New Drug Introductions in the 1980s," (with John Vernon), <u>Journal of Health Economics</u>, Vol. 13, 1994, pp. 383-406.

"Research and Development Costs for New Drugs by Therapeutic Category: A Study of the U.S. Pharmaceutical Industry," (with Joseph A. DiMasi, Ronald W. Hansen, and Louis Lasagna), PharmacoEconomics, Vol. 7, No. 2, 1995, pp. 152-169.

"Economic Evaluation of Drug Treatment for Psychiatric Disorders: The New Clinical Trial Protocol," (with Gary Zarkin, Josephine Mauskopf, Heather A. Bannerman, and Richard H. Weisler), Chapter 161, in Floyd E. Bloom and David J. Kupfer, eds., Psychopharmacology: The Fourth Generation of Progress, (Raven Press, Ltd.: NY), 1995, pp. 1897-1905.

"R&D Costs, Innovative Output and Firm Size in the Pharmaceutical Industry," (with Joseph A. DiMasi and John Vernon), <u>International Journal of the Economics of Business</u>, Vol. 2, No. 2, 1995, pp. 201-219, (special volume honoring Merton J. Peck of Yale University).

"Price and Profit Control, New Competitive Dynamics and the Economics of Innovation in the Pharmaceutical Industry," in Adrian Towse, ed., <u>Industrial Policy and the Pharmaceutical Industry</u>, (Office of Health Economics: London), 1995, pp. 77-91.

"Economic Scales and Tests," (with Ronald W. Hansen), in B. Spilker, ed., <u>Quality of Life and Pharmacoeconomics in Clinical Trials</u>, Second Edition, (Lippincott-Raven Press: Philadelphia), 1996, pp. 79-84.

"Returns to Pharmaceutical R&D: Prospects Under Health Care Reform," (with John Vernon), in Robert Helms, ed., <u>Competitive Strategies in the Pharmaceutical Industry</u>, (AEI Press: Washington, D.C.), 1996, pp. 194-207.

"Longer Patents for Increased Generic Competition: The Waxman-Hatch Act After One Decade," <u>PharmacoEconomics</u>, Vol. 10, Suppl. 2, 1996, pp. 110-123.

"The Effect of Pharmacoeconomics on Company Research and Development Decisions," Pharmacoeconomics Vol. 11, No. 5, May 1997, pp. 389-397.

"The Impact of Cost-Effectiveness on Public and Private Policies in Health Care: An International Perspective," (Edited Symposium Volume with Frank Sloan), in <u>Social Science & Medicine</u>, Vol 45, No. 4, August 1997.

"Pharmacy Benefit Management, Cost-Effectiveness Analysis and Drug Formulary Decisions," (with C. Daniel Mullins), <u>Social Science & Medicine</u>, Vol. 45, No. 4, August 1997, pp. 535-544.

"Public Policy and Innovation in Pharmaceuticals and Biotechnology," in Demetri

Kantarelis, editor, <u>Business and Economics for the 21st Century, Volume I</u>, Business and Economic Society International, Worcester, Mass., 1997, pp. 343-349.

"The Role of Cost-Effectiveness Analysis in Managed Care Decisions," Pharmacoeconomics, Vol. 14, suppl. 1, 1998, pp. 15-24.

"The Determinants of Pharmaceutical Research and Development Expenditures," (with John Vernon), <u>Journal of Evolutionary Economics</u>, Vol. 10, 2000, pp. 201-215.

"Effective Patent Life in Pharmaceuticals," (with John Vernon), <u>International Journal of</u> Technology Management, Vol. 19, Nos. 1/2, 2000, pp. 98-120.

"The Distribution of Sales from Pharmaceutical Innovation," (with John Vernon) PharmacoEconomics, Vol. 18, suppl. 1, 2000, pp. 21-32.

"Pressures from the Demand Side: Market Dynamics and Industrial Structures," (with John Vernon), in Hannah Kettler, ed., <u>Consolidation and Competition in the Pharmaceutical Industry</u>, Office of Health Economics, London, 2001, pp. 62-79.

"Returns on Research and Development for 1990s New Drug Introductions," (with John Vernon and Joe DiMasi). <u>PharmacoEconomics</u>, Vol. 20, Supplement 3, 2002.

"Patents, Innovation and Access to New Pharmaceuticals," <u>Journal of International</u> <u>Economics Law Vol 5, No. 4, December 2002, pp 849-860.</u>

"Patents and New Product Development in the Pharmaceuticals and Biotechnology Industries," in John Duca, ed., Science and Cents: the Economics of Biotechnology, <u>Federal</u> Reserve Bank of Dallas, 2003.

"The Price of Innovation: New Estimates of Drug Development Costs," (with Joseph DiMasi and Ronald Hansen). <u>Journal of Health Economics</u>, Vol. 22, 2003, pp.141-185.

"The Ripple Effects of a Restrictive Medicaid Formulary (editorial), <u>American Journal of Managed Care</u>, Vol. 9, No. 10, October 2003, pp. 648-649.

"Are the Economics of Pharmaceutical R&D Changing? Productivity, Patents and Political Pressures," Pharmaceutical R&D Changing? Productivity, Patents and Political Pressures," Pharmaceutical R&D Changing? Productivity, Patents and Political Pressures, Pharmaceutical R&D Changing? Pharmace

"R&D Costs and Returns by Therapeutic Category" (with Joseph DiMasi and John Vernon), Drug Information Journal, Vol. 38, No. 3, 2004, pp. 211-223.

"Increasing R&D Incentives for Neglected Diseases: Lessons from the Orphan Drug Act," in Maskus KE and Reichman JH, eds., International Public Goods, and Transfer of

<u>Technology Under a Globalized Intellectual Property Regime</u>, Cambridge University Press, 2005, pp. 457-480.

"Encouraging the Development of New Vaccines," <u>Health Affairs</u>, Vol. 24, No. 3, 2005, pp. 697-704.

"Extraordinary Claims Require Extraordinary Evidence," and "Setting the Record Straight on Setting the Record Straight: Response to Light and Warburton's Rejoinder," (with Joseph DiMasi and Ronald Hansen) <u>Journal of Health Economics</u>, 2005 Vol. 24, No.5, pp. 1034 and 1049.

"Developing Drugs for Developing Countries," (with David Ridley and Jeffrey Moe) Health Affairs March/April 2006 Vol. 25 No. 2, pp 313-324.

"Entry and Competition in Generic Biologics" (with David Ridley and Kevin Schulman), forthcoming in Managerial and Decision Economics, 2006.

"The Quantity and Quality of Worldwide New Drug Introductions 1982 – 2003" (with Richard Wang), Health Affairs, March/April 2006, Vol. 25 No. 2, pp. 452-460.

"Generic Competition in the U.S. Pharmaceutical Industry" (with Atanu Saha, Howard Birnbaum, Paul Greenberg, and Oded Bizan), forthcoming in <u>International Journal of the Economics of Business</u>, 2006.

"How Did the 2003 Prescription Drug Re-Importation Bill Pass the House?" (with Omar Gobcalasis, Mike Adams and Edward Tower), forthcoming in <u>Economics and Politics</u>, 2006.

"Spending on Post-approval Drug Safety" (with David Ridley, Judith Kramer, Hugh Tilson, and Kevin Schulman), in <u>Health Affairs</u>, March/April, 2006, Vol. 25 No. 2, pp. 429-436.

Papers Presented at Major Professional Conferences: (Selected Presentations since 1990)

"Brand Loyalty, Entry, and Price Competition after the 1984 Act," Applied Econometric Association Meetings, Ankara, Turkey, June, 1990; also, Second World Congress in Health Economics, Zurich, Switzerland, September 1990.

"First Mover Advantages, Price and Non-Price Competition in Pharmaceuticals," American Economic Association Meetings, December 1990.

"International Competition in Pharmaceutical R&D," National Science Board on Industrial

Support for R&D, U.S. National Science Foundation, Washington, D.C., January 1991.

"Research and Development in an Era of Global Competition," Conference on American Pharmaceuticals in the Global Village, U.S. Department of State, Washington, D.C., June 1991.

"Pharmaceutical Research and Development: Returns and Risk," Centre for Medicines Research Annual Lecture 1991, Royal College of Physicians, London, England, July 1991.

"The Effect of Medicaid Formularies on the Availability of New Drugs," Tufts University Conference, Cost Containment and Pharmaceuticals: Issues for Future Research, Talloires, France, July 1991.

"Innovative Structure and Performance of the Pharmaceutical Industry," Second International Conference on the Economics of Innovation, University of Milan, Piacenza, Italy, June 1992.

"Pharmaceuticals and Health Care Costs," International Health Care Forum on Health Care Policy and the Pharmaceutical Industry, Gotemba, Japan, October 1992.

"Innovation and Structural Change in Pharmaceuticals and Biotechnology," American Economic Association Meetings, Anaheim, California, January 1993.

"Pharmaceutical R&D Costs, Prices and Profits," Conference on Pharmaceutical Industry Research, Innovation and Public Policy, Harvard University, John F. Kennedy School of Government, February 1993.

"Pharmaceutical R&D Returns: Prospects Under Health Care Reform," American Enterprise Institute Conference on Competitive Strategies in the Pharmaceutical Industry, October 1993.

"Health Care Reform--Implications for Pharmaceutical Innovation," Drug Information Association Workshop on Health Economics, Lisbon, Portugal, November 1993.

"The Administration's Health Reform Plan--Implications for Pharmaceutical Innovation," testimony before Congressman Waxman's House Subcommittee on Health and the Environment, February 1994.

"Socially Optimal Reimbursement and Utilization Policies for Pharmaceuticals," Hungarian National Social Insurance Administration, Budapest, Hungary, April 1994.

"Pharmaceuticals and Quality of Life: An Economist's Perspective," Forum Engelberg, Engelberg, Switzerland, April 1994.

"Price and Profit Control, New Competitive Dynamics and the Economics of Innovation in the Pharmaceutical Industry," Office of Health Economics Symposium on Industrial Policy, London, England, June 1994.

"Health Reform and Pharmaceutical Innovation," American Enterprise Institute, Washington, D.C., July 1994.

"R&D Costs, Innovational Output and Firm Size," Yale University Festschrift Honoring Merton J. Peck, New Haven, Connecticut, September 1994.

"The Effects of Increased Government Purchases on Vaccine R&D," testimony before the Subcommittee on Health and the Environment on the Vaccines for Children's Program, June 1995.

"PharmacoEconomics and Pharmaceutical Innovation," to IFPMA Conference on PharmacoEconomics in the year 2000, Geneva, Switzerland, February 1995.

"Development of New Pharmaceuticals," to the Third Princeton Conference on Drug Discovery and Development, Princeton, New Jersey, May 1995.

"Longer Patents for Increased Generic Competition: The Waxman-Hatch Act After One Decade," Tufts University Conference on Cost Containment Health Care Reform and Pharmaceutical Innovation, Talloires, France, July 1995.

"The Roles of Government in the Drug Regulation Process: Lessons from Other Nations," presented to Conference on Health Financing and Health Economics, Beijing, China, October 1995.

"The Use of Cost-Effectiveness Analysis by Pharmaceutical Benefit Management Companies," to Duke University Conference on Cost-Effectiveness Analysis in Decision Making," November 1995.

"The Effects of the Waxman Hatch Act on Drug Innovation and Generic Competition," Testimony before the U.S. Senate Judiciary Committee, March 1996.

"International Patent Policies and Pharmaceutical Innovation," to University of Vienna, May 1996.

"Public Policies and Pharmaceutical Innovation" to Jagellion University, Krakow, Poland, May 1996.

"Financing Health Care in Pharmaceuticals and Biotechnology," to OECD Workshop,

Paris, July 1996.

"Health Care and Innovation" to Seminar on Approaches to Cost Containment in Health Care, Kasteel de Willenburg, The Hague, October 1996.

"Pharmaceutical Innovation, Cost-Effectiveness Research and Emerging Regulatory Issues," American Enterprise Institute, Washington, D.C., November 1996.

"The Role of Cost-Effectiveness Analysis in Managed Care," Tufts University Center for the Study of Drug Development Conference, Talloires, France, July 1997.

"Public Policy and Innovation in Pharmaceuticals and Biotechnology," Business and Economics Society International Conference, Athens, Greece, July 1997.

"The Determinants of Pharmaceutical Research and Development Expenditures," Schumpeterian Society Meetings, Vienna, Austria, June 1998.

"Effective Patent Life in Pharmaceuticals," U.S. House of Representatives Colloquium for House Staff Members, June 1999.

"The Distribution of Sales from Pharmaceutical Innovation," Schumpeterian Society Meetings, Manchester England, June, 2000.

"New Research on the Returns to Pharmaceutical R&D," American Enterprise Institute, Washington, D.C., October 2000.

"Patent Policy Issues in Pharmaceuticals" Robert Wood Johnson Foundation Colloquium on the Pharmaceutical Industry, Washington, D.C., March 2001.

"Returns to Pharmaceutical R&D in the 1990s" Tufts University Conference, Center for the Study of Drug Development, Talloires France, July, 2001.

"Patents, Innovation and Access to New Pharmaceuticals," American Association for the Advancement of Science, Annual Meetings, Boston, February 2002.

"Patents and the Development of New Pharmaceuticals in Pharmaceuticals and Biotechnology Industry," Federal Reserve Bank of Dallas, April 2002.

"Returns to Pharmaceutical R&D," American Economic Association Meetings, Washington, DC, January 2003.

"Increasing R&D Incentives for Neglected Diseases," Duke University Law School Conference, April 2003; St. Vincent's College, September 2003; Georgetown University,

October 2003, Columbia University, December 2003.

"Are the Economics of Pharmaceutical R&D Changing? Productivity, Patents, and Political Pressures," Tufts University Center for the Study of Drug Development Conference, Talloires, France, July 2003.

"Global Returns on R&D From New Drug Introductions," Keio University, Tokyo, Japan, September 2003.

"R&D Costs and Returns by Therapeutic Category," Southern Economic Association Meetings, San Antonio, Texas, November 2003.

"The Hatch-Waxman Act and Drug Innovation," Food and Drug Law Institute Conference, Washington, DC, December 2004.

"Developing Drugs for Developing Countries," American Economic Association Meetings, Philadelphia, PA, January 2005; also International Health Economics Congress, Barcelona, Spain, July 2005.

"Generic Competition in Pharmaceuticals," International Conference on Pharmaceutical Innovation, Taipei, Taiwan, May 2005.

"Impact of Generic Competition on Pharmaceutical Markets," International Health Economics Congress, Barcelona, Spain, July 2005.

Research Grants and Government Projects:

Principal Investigator, National Science Foundation Grant to Yale University, "Collaborative Research on Determinants of Selected Firm Outlays," June 1969 - December 1970. (\$9,800.00)

Principal Investigator, National Science Foundation Grant to NBER for research on "The Returns to Firm Investment Outlays, Plant and Equipment and Advertising Outlays," 1972-1974. (\$47,900.00)

Principal Investigator, National Science Foundation Grant for Research on "The Effect of Product Quality Regulation on Innovation: The Case of the U.S. Ethical Pharmaceutical Industry," 1975-1978. (\$111,700.00)

Consultant, Federal Trade Commission project on "The Effects of Repealing Anti-Substitution Laws on Drug Innovation," 1977-1978.

Study Rapporteur, National Academy of Sciences Committee on Technology and International Economic and Trade Issues, "The Impact of Government Regulation on Innovation," 1978-1979.

Principal Investigator, National Science Foundation Grant to Duke University for "Studies on Drug Substitution, Patent Policy and Innovation," 1979-1982. (\$125,979.00)

Advisory Panel Member, Office of Technology Assessment, The Patent System and Its Assessment on New Technological Enterprises, 1982-1983.

Principal Investigator, Environmental Protection Agency Grant to Investigate the Effects of Regulation on Innovation in Pesticides, (with Kip Viscusi of the Fuqua School of Business), 1983-1984.

Member, Committee on Public-Private Sector Relations in Vaccine Innovation," Institute of Medicine, National Academy of Sciences, 1983-1985.

Principal Investigator, General Accounting Office, Research Project on the Effects of Different State Regulations on Automobile Insurance Premiums and Availability, 1984-1985.

Principal Investigator, Duke University, Program in Pharmaceuticals and Health Economics, Project on Cost Containment and Pharmaceutical Innovation, 1985-1991.

Principal Investigator, Duke University, Program in Pharmaceuticals and Health Economics, Project on Returns to Pharmaceutical R&D, 1990-1994.

Principal Investigator, Program in Pharmaceuticals and Health Economics, "Public Policy and Innovation in the Vaccine Industry," 1995-1997.

Principal Investigator, Program in Pharmaceuticals and Health Economics, "New Research on the Costs and Returns to R&D," 1998-2002.

Principal Investigator, "Increasing R&D Incentives for Neglected Diseases," 2002-2005.

Henry Grabowski

May 30, 2007

Companies for which I have consulted over the past year

Allergan
Amgen
Astra-Zeneca
Brystol-Myers Squibb
Elan Pharmaceuticals
Endo Pharmaceuticals
Fujisawa Pharmaceuticals
Genentech
Glaxo-SmithKline
Johnson & Johnson
Merck
Novartis
Pfizer
Roche
Shire Pharmaceuticals
UCB
Valeant Pharmaceuticals
Warner-Chillcott
Wyeth

Exhibit 3

Testimony Since 2003:

Arbitration hearing, NeoPharm, Inc. v. Pharmacia & Upjohn Co., Washington, DC, December 2003 (confidential).

Deposition, New River Pharms v DSM Pharms, U. S. District Court for the Eastern District of Tennessee, March 2004.

Deposition, Sanofi-Synthelabo et. al v. Apotex, Inc., U. S. District Court for the Southern District of New York, November 2004.

Deposition, In re Bristol-Myers Squibb Securities Litigation, Civil Action No. 00-1990, (SRC) U. S. District Court for the District of New Jersey, January 2005.

Deposition, Wyeth v. Teva Pharmaceuticals, Civil Action No., 03-1293 (KSH), U. S. District Court for the District of New Jersey, June 2005.

Deposition, *Xcel Pharmaceuticals v. Kali Laboratories*, U. S. District Court for the District of New Jersey, May 2006.

Deposition, Pfizer Inc. v. Teva Pharmaceuticals, U.S. District Court for the District of New Jersey, Civil Action No. 04-754 (JCL) August 2006. The strong December 2006

Deposition, Arbitration Hearing, Elan Pharmaceuticals v. King Pharmaceuticals, New York, NY August 2006.

Arbitration Testimony, Elan Pharmaceuticals v. King Pharmaceuticals, New York, NY September 2006.

Deposition, UCB S.A., et al., v. Mylan Laboraries, Inc., et al., United States District Court for the Northern District of Georgia, Civil Action No: 1:04-CV-0683 (WSD) December 2006.

Deposition, State of Colorado, et al., v. Warner Chilcott Holdings Company III, LTD., et al., United States District Court for the District of Columbia, Civil Action No: 1:05CV02182 (CKK) January 2007.

Exhibit B

CV of Dr. Hollander

CURRICULUM VITAE

ERIC HOLLANDER, MD, DFAPA, FACNP

Present Positions: Esther and Jo

Esther and Joseph Klingenstein Professor and Chair

Director-NIH STAART Greater New York Autism Center of Excellence

Director-Seaver Autism Research Center

Director-Compulsive, Impulsive and Anxiety Disorders Program

Director-Clinical Psychopharmacology

Department of Psychiatry

Mount Sinai School of Medicine One Gustave L. Levy Place, Box 1230

New York, N.Y. 10029

Telephone Number:

212/659-8287 212/987-4031

FAX Number: E-Mail:

eric.hollander@mssm.edu

Born:

Los Angeles, California (6/19/57)

Education:

1978

B.A.

Brandeis University, Waltham, MA

1982

M.D.

State University of New York

Downstate Medical College, Brooklyn, NY

Internship:

1982 - 1983

Internal Medicine

Mount Sinai Hospital, NY, NY

Residency:

1983 - 1986

Psychiatry

Mount Sinai Hospital, NY, NY

1985 - 1986

Chief Resident-

Clinical Research Unit and

Psychiatry Research Alzh

Alzheimer's Disease Research Center -Mount Sinai School of Medicine, NY, NY

Fellowship:

1986 - 1988

NIMH Psychiatry Research Fellowship Columbia University College of Physicians & Surgeons and NYS Psychiatric Institute

1988 - 1989

Dana Foundation Fellow

Columbia University

1988 - 1993

NIMH Research Scientist Development Award Columbia University

Licensure:

New York State License: 155389

Year: 1983

DEA License: AH2289420

Diplomate - American Board of Psychiatry and Neurology (29504) 1987

Honors:

2007, William A. Console, MD Master Teacher Award in Psychiatry Alumni Association, College of Medicine, SUNY Downstate Medical Center

2005, Best Doctors, NY Magazine

2005, Chair - NIH STAART Autism Steering Committee

2005, Secretary/Treasurer - International Society for Research In Impulsivity (ISRI)

2005, Director – International College of Obsessive Compulsive Spectrum Disorders (ICOCS)

2005, Chair – DSM-V Research Planning Agenda Workgroup on Obsessive Compulsive Behavior Spectrum Disorders

2005, Member - APA Practice Guidelines - Obsessive Compulsive Disorder

2003, Distinguished Fellow - American Psychiatric Association

2003, Substance Abuse and Mental Health Administration (SAMHSA)
National Registry of Effective Prevention Programs (NREPP), U.S. Department
Of Health and Human Services

2003, Best Doctors, New York Magazine

2002, Fellow - American College of Neuropsychopharmacology

2002 - present, Chair - DSM-V Work Group on Obsessive Compulsive Spectrum Disorders, APA

2002, Best Doctors In America

2002, Autism Clinical Trials Task Force, Cure Autism Now (CAN)

2002, Best Doctors, New York Magazine

2001, Best Doctors, New York Magazine

2001, Best Doctors, New York Post

2000-2001, Society of Biological Psychiatry, George N. Thompson Award Committee

1999, Fellow, American Psychiatric Association

1998, NARSAD Distinguished Investigator Award

1998, Full Membership, American College of Neuropsychopharmacology

1999, Section Editor, ACNP, <u>Neuropsychopharmacology: The Fifth Generation of Progress</u>

1998, DSM-IV-R Work Group Chair, Impulse Control Disorder Section

1998, Nolan D.C. Lewis Visiting Professor and Scholar, Carrier Foundation

1997, Scientific Director, CNS Research Foundation

1996, Founding Editor

CNS Spectrums: The International Journal of Neuropsychiatric Medicine

1996, Scientific Advisory Board, Anxiety Disorders Association of America

1994, Best Mental Health Specialists in the U.S.A. - Good Housekeeping

1994, The Best Doctors in America, Woodward/White, Inc.

1993, Chairman, OC Foundation Awards Committee

1993, International OCD Council Founding Member

1993, Secretary, OCD Section, World Psychiatric Association

1992, Member, DSM-IV Work Group - Obsessive Compulsive Disorder

1992, Member, DSM-IV Work Group - Body Dysmorphic Disorder

1992, Scientific Advisory Board, OC Foundation

1991, American College of Neuropsychopharmacology, Associate Member

1990, American Psychiatric Association/Wisnieski Young Psychiatrist Research Award, First Place, New York, NY

1990, Collegium Internationale Neuro-Psychopharmacologium Rafaelsen Fellowship Award, Kyoto, Japan

1988-1993, Research Scientist Development Award National Institute of Mental Health

1988-1989, Dana Foundation Fellow (Columbia University)

1986, American Psychiatric Association/Penwalt Resident Research Award, First Place, Washington, DC

1986, Marcel Heiman Memorial Award for Outstanding Research Mount Sinai School of Medicine, Department of Psychiatry

1986, M. Ralph Kaufman Prize, Outstanding Resident in Psychiatry Mount Sinai School of Medicine, Department of Psychiatry

1985-1986, Solomon W. Ginsburg Fellow: Group for the Advancement of Psychiatry

1978, General Honors, Brandeis University

Patents and Inventions:

Oxytocin in Autism and Social Attachment Disorders (US patent issued)

Mementine in Autism, Compulsive and Impulsive Disorders (US patent application)
Fluoxetine in Autism (Orphan Designation: Food and Drug Administration)
Internet Addiction - YBOCS (US Copyright)
Pathological Gambling — YBOCS (US Copyright)
Fluvoxamine Gambling Treatment Program (SAMHSA)

Founding Editor: CNS Spectrums: The International Journal of Neuropsychiatric Medicine

Editorial Advisory Board: Neuropsychopharmacology (1997 – 1999)

Research In Autism Spectrum Disorders

World Journal of Biological Psychiatry

Medscape Psychiatry & Mental Health

Psychiatric Annals

Focus on OCD

Primary Psychiatry (past)

Mental Fitness

International Journal of Psychiatry in Clinical Practice

Journal of Gambling Studies

Wager

Clinical Neuropsychiatry

Contemporary Psychiatry

Mount Sinai Journal of Medicine (Associate Editor)

Reviewer: Archives of General Psychiatry

American Journal of Psychiatry

Biological Psychiatry

Psychiatry Direct

Psychiatry Research

Journal of Neuropsychiatry and Clinical Neuroscience

Journal of the American Medical Association

Journal of Nervous and Mental Disorders

Hospital Appointments:

1986 - 1992 Assistant Attending Psychiatrist, The Presbyterian Hospital

1992 - 1993	Associate Attending Psychiatrist, The Presbyterian Hospital
1988 - 1993	Attending Psychiatrist, The New York State Psychiatric Institute
1988 - 1993	Director, Obsessive Compulsive Disorder Biological Studies Program The New York State Psychiatric Institute
1989 - 1993	Director, Anxiety Diagnostic & Recruitment Unit, NYS Psychiatric Institute
1993 - 1994	Associate Director, Academic Affairs, Queens Hospital Center
1993 - 1994	Vice Chairman, Department of Psychiatry, Mount Sinai School of Medicine
1993 - Present	Director, Clinical Psychopharmacology, Mount Sinai School of Medicine
1994 - 2003	Clinical Director, Seaver Autism Research Center
1994 - Present	Director, Compulsive, Impulsive and Anxiety Disorders Program
1996 - Present	Attending Psychiatrist, The Mount Sinai Hospital
2003 - Present	Director, Seaver Autism Research Center
2003 - Present	Director, Greater NY Autism Research Center of Excellence
Academic Appointments:	
1986 - 1988	Instructor in Clinical Psychiatry, Columbia University P & S
1988 - 1992	Assistant Professor of Clinical Psychiatry, Columbia University P & S
1992 - 1993	Associate Professor of Clinical Psychiatry, Columbia University P & S
1993 - 1996	Associate Professor of Psychiatry, Mount Sinai School of Medicine

Teaching (Mount Sinai School of Medicine and Columbia University P & S):

Professor of Psychiatry, Mount Sinai School of Medicine

Phenomenology Course -- PGY II Residents

Neuroscience Course - PGY III Residents

1996 - Present

Outpatient Psychopharmacology Course - PGY III Residents

Psychopharmacology Supervision - PGY III Residents

Anxiety Disorder Lectures - MS I and MS II Medical Students

OCD Lectures - PGY II and III Psychiatry and Neurology Residents

Neuroscience Review Course - Neurology Department

Outpatient Psychopharmacology Clinic - PGY III Residents

OCD CME Course Director - 8 Conferences at Mt. Sinai and Columbia

Journal Club and Grand Rounds - chair, Mt. Sinai/Queens Hospital Center

Pharmacology Lectures - MS IV Medical Students

Chairman and Organizer, 7 Conferences on the Diagnosis, Neurobiology, Genetics and Treatment of Autism in association with CAN, NAAR, ASA, and NARSAD

Chairman and Organizer

First International Conference on OCD, Capri, March 1993
Second International Conference on OCD, Guadaloupe, March 1996
Third International Conference on OCD, Madeira, Portugal, 1998
Fourth International Conference on OCD, St. Thomas, V.I., 2000
Fifth International Conference on OCD, Sardinia, 2001
Sixth International Conference on OCD, Lanzarote, 2003

Participant, Anxiety Disorders in African-Americans Conference, 1993

Fellowship Supervisor, Program for Minority Research Training in Psychiatry American Psychiatric Association

Professional Organizations:

Academia, Medicina & Psychiatria Foundation (Fellow)

American College of Neuropsychopharmacology

Fellow (2002) Member (1998-Present)

Finance Committee (1999-present)

Section Editor, ACNP, Psychopharmacology: The Fifth Generation of Progress

Editorial Advisory Board, Neuropsychopharmacology

Associate Member (1992-1996)

American Federation for Clinical Research

American Medical Association

American Psychiatric Association (Distinguished Fellow)

Member, Committee on Resident Research Award Review

American Psychopathological Association

American Society of Clinical Psychopharmacology

Anxiety Disorders Association of America (Scientific Advisory Board)

Asociacion Argentina de Trastornos de Ansiedad

Collegium Internationale Neuro-Psychopharmacologicum

European College of Neuropsychopharmacology - Corresponding Member

Group for the Advancement of Psychiatry

Solomon Ginsburg Fellow (1985-1986), Medical Education Committee

International College of Obsessive Compulsive Spectrum Disorders (Company Director)

International Council on OCD (Founding Member)

International Society for Research on Impulsivity and Impulse Control Disorders President Elect - 2006 (Secretary Treasurer - FY2005)

National Board of Medical Examiners (Test Material Development Committee)

Obsessive Compulsive Foundation (Scientific Advisory Board)

Society of Biological Psychiatry
Scientific Program Committee
George N. Thompson Award Committee

World General Medical Council (Fellow)

World Health Organization Committee on Priority Treatments for Mental Health Disorders Priority Treatments for Obsessive Compulsive Disorder

Consulting:

US Congress and Senate, Joint Committee on NIH Funding Issues

Psychopharmacology Consult, Health and Hospitals Corporation

Scientific Advisory Boards

Obsessive Compulsive Foundation
Anxiety Disorders Association of America
CNSR Foundation
Autism Society of America Foundation
QSAC
NAMI
Cure Autism Now

Scientific Advisory Boards

Solvay Pharmaceuticals
Abbott Neuroscience
Wyeth-Ayerst Laboratories
SmithKline Beecham
Lilly Neuroscience
Ortho-McNeil
Roche Laboratories
Pfizer Pharmaceuticals
Pharmacia/Upjohn
Callisto Pharmaceuticals, Inc.
Somaxan Pharmaceuticals

Medical Lecture Program/Speakers Program Abbott Pharmaceuticals Bristol Myers/Squibb Pharmaceuticals Eli Lilly and Company

Forrest Pharmaceuticals GlaxoSmithKline Novartis Pharmaceuticals Pfizer Pharmaceuticals Pharmacia/Upjohn Smith Kline Beecham Solvay Pharmaceuticals Wyeth Ayerst Laboratories

First International OCD Conference Organizer - Solvay/Upjohn - 1993, Capri Second International OCD Conference Organizer - Solvay/Upjohn - 1996, Guadaloupe Third International OCD Conference Organizer - Solvay/Upjohn - 1998, Madeira Fourth International OCD Conference Organizer - Solvay/Upjohn - 2000, St. Thomas Fifth International OCD Conference Organizer - Solvay/Upjohn - 2001, Sardinia First, Second, Third Columbia University OCD Conference Organizer - Ciba Geigy/CME First Mt. Sinai/OC Foundation OCD Conference - 1994 - Solvay/Upjohn First, Second, Third Mt. Sinai/Seaver Center Autism Conference First Mt. Sinai/Seaver Center Autism Conference for Educators

Administrative:

Director, Anxiety Diagnostic and Recruitment Unit MHCRC, New York State Psychiatric Institute

Director, Compulsive and Impulsive Disorders Program New York State Psychiatric Institute

Director, Open Treatment Component Mental Health Clinical Research Center New York State Psychiatric Institute

Member, Quality Assurance Committee
New York State Psychiatric Institute
Queens Hospital Center

Member, Incident Review Committee
New York State Psychiatric Institute

Member, Medical Staff Committee
New York State Psychiatric Institute
Queens Hospital Center

Member, Continuing Medical Education Committee
Columbia University, College of Physicians and Surgeons

Member, Medical Education Committee, Medical Ethics Group for the Advancement of Psychiatry

Member, Scientific Program Committee Society for Biological Psychiatry

Consultant, Health and Hospitals Corporation Psychopharmacology Issues

Member, Managed Care Committee - Psychiatry Mount Sinai School of Medicine Member, Operating Committee

Mount Sinai School of Medicine

Member, Continuing Medical Education Committee, Postgraduate School Mount Sinai School of Medicine

Member, Promotions Committee

Mount Sinai School of Medicine

Chair, Outpatient Psychiatry Research Committee Mount Sinai School of Medicine

Chair, Psychiatry Research Incident Review Board Mount Sinai School of Medicine

Chair, Space Appropriations Committee, Psychiatry Outpatient Research Center, Atran E Mount Sinai School of Medicine

Member, Special Investigation Committee-Scientific Integrity Mount Sinai School of Medicine

Member-Internal Committee-Neurology Departmental Review Mount Sinai School of Medicine

Co-Chair-Planning Committee-Institute for Brain Disorders

Patient Advocacy Groups

Obsessive-Compulsive Foundation
Member, Scientific Advisory Board
Director, Scientific Awards Committee
Member, Minorities and Research Committee

International Obsessive-Compulsive Council Founding Member Secretary

Anxiety Disorders Association of America Member, Scientific Advisory Board

World Psychiatric Association, Section on Anxiety and OCD Secretary

Cure Autism Now,

Chair, Scientific Advisory Group – Treatment Guidelines Chair, Autism Clinical Trials Task Force (ACTTF) Chair – Clinical Trials Network (CTN)

Committees

Incident Review Committee - NYS Psychiatric Institute
Faculty Staff Committee - NYS Psychiatric Institute
Quality Assurance Committee - NYS Psychiatric Institute, Queens Hospital Center
Chairman - Grand Rounds Committee - Queens Hospital Center
Chairman - Journal Club Committee - Queens Hospital Center

Operating Committee - MSSM Psychiatry Department
Senior Investigators Committee - MSSM Psychiatry Department
Clinical Directors Committee - MSSM Psychiatry Department
Affiliate Clinical Directors Committee - MSSM Psychiatry Department
Trauma Committee - Victim Services, Inc.
Trauma Planning Subcommittee - Victim Services, Inc.
Service Directors Committee - Queens Hospital Center
Managed Care Committee - Mt. Sinai School of Medicine
Continuing Medical Education Committee - Mt. Sinai School of Medicine
Promotions Committee - Mt. Sinai School of Medicine

Grant Reviewer

NIMH – 1996-2005 - RO1, K grants, RUPP-PI NIDA – 1995-2003 - RO1, K grants

Current Funded Grants:

Principal Investigator

(2003-2008). NIH – <u>Greater New York Autism Research Center of Excellence:</u> <u>The STAART Program</u>. (1 U54 MH66673-01). Annual Direct Cost \$ 1,417,295 Total Direct Cost \$ 7,149,157.

(2003-2008). NIH – <u>Greater New York Autism Research Center of Excellence:</u> <u>The STAART Program</u>. (1 U54 MH66673-01). Liquid Citalopram Supplement. Annual Direct Cost \$ 100,000.

(2003-2008). <u>NIMH</u> - <u>NRSA Institutional Research Training Grants</u> – Training in Psychopharmacology and Outcomes Research (1 T32 MH62996-01). Annual Annual Direct Cost \$ 50,127 Total Costs \$ 455,353.

(2005-2008). <u>FDA</u> – Fluoxetine in Pediatric Body Dysmorphic Disorder (FD-R-002613-01) Annual Direct Cost \$ 289,387 Total Direct Cost \$ 884,873.

(1994-2007). <u>Seaver Foundation</u> - Seaver Autism Research Center (Eric Hollander, M.D., Director) Annual Cost \$ 1,250,000 Total Cost \$ 13,000,000.

(2007-2009) <u>UJAFJP</u> – Seaver Center Social Skills Project Annual Direct Cost \$ 74,166

(2006-2007). <u>CAN</u> – Clinical Trials Network Infrastructure. Annual Direct Cost \$ 102,488 Total Direct Cost \$ 112,737.

(2006-2007). <u>CAN</u> – A multi-site double-blind placebo-controlled trial of memantine vs. placebo in children with autism targeting motor skills. Annual Direct Cost \$ 54,393 Total Direct Cost \$ 59,842.

(2006-2008). <u>BMS</u> – Aripiprazole Treatment in Children with Autistic Disorder Annual Direct Cost \$ 19,835

Co-Principal Investigator

(2000-2004). <u>CDC</u> – Pharmacotherapy of Sexually Compulsive MSM – Jonathan Morgenstern, PI, Annual Direct Cost \$ 244,172 Total Direct Cost \$ 712,324.

(1998-2003). Solvay Pharmaceuticals - Brain Imaging of the Effects of Lithobid and Lithium Carbonate In Bipolar and Cyclothymic Patients - Monte Buchsbaum, PI, Total Direct Cost \$ 252,000.

Co-Investigator

(2000-2006). <u>NIDA</u> – Interdisciplinary Training In Drug Abuse Research (T32 DA 07135-21) – Stuart C. Sealfon, M.D., P.I., Annual Direct Cost \$ 359,568 Total Direct Cost \$ 1,797,840.

Pending Grants:

Principal Investigator

NIH - Mount Sinai Interdisciplinary Developmental Science Award

NIMH – Lithium vs. Naltrexone vs. Placebo in Impulse Dyscontrol (Pathological Gambling)
Annual Direct Cost \$ 225,000 Total Direct Cost \$ 381,375

<u>NIMH</u> – Efficacy and Safety of Risperidone Augmentation in SRI-Resistant OCD Annual Direct Cost \$ 225,000 Total Direct Cost \$ 381,375

Prior Funded Grants

(2001-2006). <u>FDA</u> - Fluoxetine vs. Placebo In Adult Autistic Disorder. (FD-R-002026-01) Annual Direct Cost \$ 203,771 Total Direct Cost \$ 607,930.

(2001-2006). NINDS - Divalproex Sodium/Placebo In Child/Adolescent Autism. (1 R21 NS43979-01) Annual Direct Cost \$ 100,000 Total Direct Cost \$ 300,000.

(1998-2003). <u>FDA</u> - Liquid Fluoxetine vs. Placebo in Child/Adolescent Autism. (FD-R-001404-01) Annual Direct Cost \$116,242 Total Direct Cost \$349,637 Total Cost \$592,635.

(1999-2003). NIMH - Pharmacotherapy of Adolescent Body Dysmorphic Disorder (1 RO1 MH58935-01A1) Annual Direct Cost \$ 66,578 Total Direct Cost \$ 112,850 Total Cost \$ 475,247.

(2002-2003). <u>Abbott Laboratories</u> – An Open-Label Trial of Divalproex Sodium Extended Release In Borderline Personality Disorder. Total Direct Cost \$ 143,115.00.

(2001-2003). <u>Pfizer Pharmaceuticals</u> – Efficacy of Sertraline in the Treatment of Binge Eating Disorder Among Obese Children and Adolescents. Total Direct Cost \$ 50,000.

(2001-2003). <u>Forrest Laboratories</u> – Treatment of Internet Addiction with Citalopram. Total Direct Cost \$ 50,000.

(2001-2003). <u>Contral Pharma</u> – Nalmefene in the Treatment of Pathological Gambling: A Placebo Controlled Dose Reponse Study. Total Direct Cost \$ 100,000.

(2001-2003). <u>Pfizer</u> – Multicenter Trial of Ziprasidone Augmentation in Serotonin Reuptake Inhibitor-Resistant Obsessive-Compulsive Disorder. Total Direct Cost \$ 144,663.

(2001-2003). <u>Callisto</u> – Autoimmune Investigations In Obsessive-Compulsive Disorders. Total Direct Cost \$ 10,000.

(2001-2003). Pfizer - Phase II, Twelve Week, Double Blind and Placebo Controlled Study

To Evaluate the Safety and Efficacy of Two Doses of CP-448,187 (1.5mg and 3.0mg) In Subjects with Obsessive Compulsive Disorder. Total Direct Cost \$ 100,000.

(1998-2003). <u>Abbott Laboratories</u> – Divalproex Sodium vs. Placebo In Childhood/Adolescent Autism: A Double-Blind Placebo Controlled Study Followed by Fluoxetine Augmentation. Total Cost \$ 86,000.

(1998-2003). <u>Lilly Laboratories</u> – Olanzapine vs. Placebo Crossover Study of Autistic Disorder: Effect of fMRI Imaging. Total Cost \$ 150,000.

(1998-2003). <u>Bristol-Myers Squibb</u> - Serzone Treatment Study in Pathological Gambling. Total Direct Cost \$ 40,000.

(1998-2003). Solvay Pharmaceuticals - Double-Blind Parallel Trial of Lithobid, Lithium Carbonate and Placebo In Lithium Treatment Naive Bipolar and Cyclothymic Patients Presenting To A Pathological Gambling Clinic. Total Annual Direct Cost \$ 127,306 Total Cost \$ 254,612.

(1998-2003). <u>PBO Foundation</u> - Research and Clinical Program for OCD and Related Disorders. Total Annual Direct Cost \$ 90,910.

(1997-2003). <u>Janssen Pharmaceuticals</u> - Risperidone in Refractory OCD: Positron Emission Tomography Imaging. Annual Direct Cost \$ 120,000.

(1995-2003). <u>Lilly Research Labs</u> - Prozac and Regional Metabolic Activity in Autism. Total Direct Cost \$ 30,000.

(1998-2003). Smith-Kline Beecham – A Double-Blind Placebo-Controlled Flexible Dose Study of the Efficacy and Tolerability of Paroxetine on Generalized Anxiety Disorder. Total Direct Cost \$ 60,120.

(1999-2003). Solvay Pharmaceuticals – A Multicenter, Double-Blind, Randomized, Parallel Group Study of the Efficacy and Safety of a Flexible Dose Regimen of Fluvoxamine CR versus Placebo in Outpatients with Obsessive Compulsive Disorder. Total Direct Cost \$ 100,000.

(1999-2003). <u>Abbott Pharmaceuticals</u> – Divalproex Sodium vs Placebo in Intermittent Explosive Disorder. Total Direct Cost \$ 100,000.

(1999-2003). <u>Solvay Pharmaceuticals</u> – Fluvoxamine vs. Placebo In the Treatment of Generalized Social Phobia. Total Direct Cost \$ 100,000.

(1998-2002). NIMH - Divalproex Sodium/Placebo In Borderline PD (1 RO3 MH56974-01). Annual Direct Cost \$ 49,988 Total Direct Cost \$ 99,762 Total Cost \$ 169,097.

(1997-2002). NIDA - Serotonergic/Norepinephrine Function in Pathological Gambling. (1 RO1 DA10234-01A2) Annual Direct Cost \$ 251,126 Total Direct Cost \$ 984,926 Total Cost \$ 1,669,450.

(1997-2001). <u>Glaxo-Wellcome</u> - Sumatriptan Challenge In Autism and Asperger's Disorder. Total Direct Cost \$ 50,000.

(1998-2000). <u>Cure Autism Now</u> - Fluoxetine/Placebo Treatment of Childhood/Adolescent Autism: Clinical Predictors & Dimensional Severity. Total Cost \$ 56,100.

- (1998-1999). <u>Cure Autism Now</u> D8/17 Positivity in Autism: Implications for Etiology, Subtyping and Treatment. Total Cost \$ 15,000.
- (1998-1999). NARSAD Distinguished Investigator Award D8/17 Positivity in Autism: Implications for Etiology, Subtyping and Treatment. Total Cost \$ 85,525.
- (1988-1993). <u>NIMH Research Scientist Development Award</u> "Psychobiology of Obsessive Compulsive and Related Disorders", NIMH. MH-00750. Annual Costs \$ 72,150, Total Costs \$ 360,750.
- (1994-1997). <u>FDA</u> Orphan Drug Grant Clomipramine/Desipramine Crossover in BDD (FD-R-000941-01) Annual Direct Costs \$ 198,871 Total Direct Cost \$ 398,600
- (1995-1998). <u>Abbott Pharmaceuticals</u> Valproate Treatment of Borderline Personality Disorder. Total Direct Cost \$ 25,000.
- (1997-1998). <u>SmithKline Beecham Pharmaceuticals</u> A Double-Blind, Placebo-Controlled, Flexible Dosing Trial to Evaluate the Efficacy of Modified Release Paroxetine In the Treatment of Panic Disorder. Annual Direct Cost \$ 25,000.
- (1997-1998). <u>Upjohn Pharmaceuticals</u> Double Blind Placebo Controlled Fluvoxamine Treatment of Pathological Gambling. Annual Direct Cost \$ 100,000.
- (1994-1996) <u>Upjohn Pharmaceuticals</u> Double Blind Placebo Controlled Fluvoxamine Treatment of Pathological Gambling. Annual Direct Cost \$ 100,000.
- (1993-1994). <u>Solvay Pharmaceuticals</u> Fluvoxamine/Clomipramine Treatment of OCD. Annual Direct Cost \$ 52,500.
- (1992-1993). Smith Kline Pharmaceuticals Effect of Paroxetine on SPECT/Cerebral Blood Flow in OCD. Annual Direct Cost \$ 15,000.
- (1989-1994). Mental Health Clinical Research Center (NIMH) Open Treatment Component (DF Klein, PI) \$ 200,420.
- (1990-1992). <u>American Psychiatric Association/McArthur Foundation</u> DSM-IV Field Trial for Obsessive-Compulsive Disorder. Annual Direct Cost \$ 10,000.
- (1991-1993). <u>Smith Kline Beecham Pharmaceuticals</u> Paroxetine Treatment of Obsessive-Compulsive Disorder. Annual Direct Cost \$ <u>100,000</u>.
- (1990-1991). <u>Child Psychiatry Research Center Grant</u> Psychobiology of Childhood Obsessive-Compulsive Disorder. \$ 2,220.
- (1990-1991). Child Psychiatry Research Center Grant Follow-up Study: Collaborative Perinatal Project Soft Signs and Anxiety Disorders. \$2,000.
- (1990-1991). <u>Biomedical Research Support Grant</u> Research Foundation for Mental Hygiene to New York State Psychiatric Institute. Psychobiology of Impulsive Personality Disorders. \$ 3,000.
- (1988-1989). <u>Biomedical Research Support Grant</u> Research Foundation for Mental Hygiene to New York State Psychiatric Institute. 5HT Enhanced Cerebral Blood Flow and Auditory Evoked Potentials and Repeat Challenges During Treatment in OCD. \$ 6,200.

(1988-1989). <u>Biomedical Research Support Grant</u> - Columbia University College of Physicians and Surgeons. Apomorphine Challenges in Cocaine Abuse. \$ 5,000.

(1987-1988). <u>Biomedical Research Support Grant</u> - Research Foundation for Mental Hygiene to New York State Psychiatric Institute. Biological Challenges in Normal Controls. \$ 4,500.

(1987). <u>Biomedical Research Support Grant</u> - Research Foundation for Mental Hygiene to New York State Psychiatric Institute. Biological Challenges in Obsessive-Compulsive Disorder. \$3,642.

(1987). <u>Biomedical Research Support Grant</u> - Research Foundation for Mental Hygiene to New York State Psychiatric Institute. Neuropsychiatric Investigations of Obsessive-Compulsive Disorder. \$ 4,964.

B. Co-Principal Investigator

<u>NIMH</u> - MH43845-Psychobiology of Obsessive Compulsive Disorder. 35% Effort. (Dr. M. Liebowitz, PI), Total Direct Costs \$ 356,412.

<u>NIMH</u> - MH44175-A Family Study of Obsessive Compulsive Disorder. 10% Effort. (Dr. Abby Fyer, PI). Total Direct Costs \$ 464,798.

(1991). Biomedical Research Support Grant - Research Foundation for Mental Hygiene - Neuropharmacology and Neuropsychology of Pathological Gambling. (C. DeCaria, PI). \$4,490.

(1991). Biomedical Research Support Grant - Research Foundation for Mental Hygiene - CT Findings and Soft-Signs in OCD (D. Stein, PI). \$ 2,000.

C. Director

Mental Health Clinical Research Center (NIMH). Anxiety Diagnostic and Recruitment Center Component (DF Klein, PI). \$ 508,000.

D. Co-Investigator

<u>NIMH</u>-Endogenous ERP's in Obsessive Compulsive Disorder. RO1 Grant. (J. Towey, PI) Total Direct Costs \$ 133,461.

<u>NIMH</u>-Chlorimipramine and Behavior Therapy for Obsessive Compulsive Disorder. RO1 Grant. (M. Liebowitz, PI) Total Direct Costs \$ 766,224.

(1988-1989). <u>Biomedical Research Support Grant</u> - Research Foundation for Mental Hygiene to New York State Psychiatric Institute. M-CPP Challenge in Eating Disorders (C. Buttinger, PI) \$ 5,000.

E. Overall Preceptor

NAAR/Bristol-Myers Squibb Research Fellowship in Autism and Neuropharmacology Neuropharmacology, Neuroimaging, Immunology, Molecular Biology, and Molecular Genetics Charles Cartwright, M.D. Total Annual Direct Cost \$ 60,000

NAAR/Bristol-Myers Squibb Research Fellowship in Autism and Neuropharmacology Neuropharmacology, Neuroimaging, Molecular Neurobiology Sherie Novotny, M.D. Total Annual Direct Cost \$ 60,000

Prior Co-Investigator

(1996-2000). <u>NIMH First Award</u> - Fluoxetine vs. Placebo Treatment of Depersonalization Disorder (MH55582) - Daphne Simeon, PI, Annual Direct Cost \$ 70,000.

(1996-1998). <u>Theodore & Vada Stanley Foundation</u> - Positron Emission Tomography and Emotion Interpretation in Autistic Adults - Bonnie Aronowitz, PI, Annual Direct Cost \$ 64,000.

Selected Presentations:

Over 300 scientific presentations at American Psychiatric Association, Society of Biological Psychiatry, American College of Neuropsychopharmacology, World Federation of Societies of Biological Psychiatry, Psychiatry Research Society, International Catecholamine Conf, Neuropharmacology of Serotonin Conf, AEP, CINP, ECNP and at many grant rounds at psychiatry departments in the USA and Europe/South America/Africa.

Chairman-Scientific Symposium

1988	Society of Biological Psychiatry - "Obsessive Compulsive Disorders"
1989	American Psychiatric Association - "Predictors of Treatment Outcome in OCD"
1989	American Psychiatric Association - "Overlap of Tourette's Syndrome & OCD"
1989	World Federation Societies Biological Psychiatry
1,00	"Update on Drug Treatment of OCD" and "Psychobiology of OCD"
1990	American Psychiatric Association - "Update on the Treatment of OCD"
1990	American Psychiatric Association - "Overlap of Eating Disorders and OCD"
1991	Columbia University CME - "New Directions in OCD"
1992	American Psychiatric Association - "Obsessive-Compulsive Related Disorders"
1992	American Psychiatric Association - "Impulsivity and Compulsivity"
1993	First International OCD Conference, Capri
1993	American Psychiatric Association - "OCD Spectrum Disorders"
1994	American Psychiatric Association - "OCD Spectrum" and "Neuropsychology of OCD"
1994	CINP, Washington, DC - "New Developments: Functional Imaging of OCD and TS"
1995	American Psychiatric Association -
175.0	"Overview and Psychopharmacology of Body Dysmorphic Disorder"
	"Impulsivity and Compulsivity: Phenomenology and Treatment"
1996	American College of Neuropsychopharmacology -
	"Oxytocin in Neuropsychiatric Illness: Studies Relevant to Autism";
*	"Strategies for Defining a More Homogeneous Phenotype of Autism for Family/
	Genetic Studies"
1996	American Psychiatric Association - "OCD: State of the Art and Practical Management"
1997	American Psychiatric Association -
	"Gambling: Biological/Genetic, Treatment, Government and Gaming Concerns"
	"Predictors of Treatment Response in Mood and OCD-Related Disorders"
	"Recent Advances in Autism and Asperger's Disorder"
	"CNS Spectrums - Emerging Neuropsychiatric Concepts"
1998	American Psychiatric Association –
	"Genetics of OCD"
1998	American College of Neuropsychopharmacology
	"Neuropsychopharmacology of Pathological Gambling"
1999	American Psychiatric Association –
	"New Perspectives in the Treatment of Impulsivity"
2000-2	005
	Multiple symposia at APA, ACNP, NCDEU annual meetings

Fellows:

1. Dan J. Stein, M.D.

Columbia University/NYS Psychiatric Institute Postdoctoral Research Fellow NARSAD Young Investigator Award - "Psychobiology of the Personality Dimensions"

2. Daphne Simeon, M.D.

Columbia University/NYS Psychiatric Institute Postdoctoral Research Fellow NIMH Postdoctoral Research Fellowship NARSAD Young Investigator Award - "Depersonalization: Diagnosis, Biology, Treatment"

3. Michael Hwang, M.D.

Program for Minority Research Training in Psychiatry, American Psychiatric Association "Neurological Aspects of OCD and TS"

4. Allison McCarley

Program for Minority Research Training in Psychiatry, American Psychiatric Association "Sexual Side Effects of Serotonin Reuptake Blockers: Stanley Scholar Program, Columbia University

5. Robert Grossman, M.D.

NIMH Postdoctoral Research Fellow - Mt. Sinai School of Medicine Psychobiology of Self-Injurious Behavior

Scott Cherkasky, M.D.
 Mt. Sinai Geriatric Research Fellow
 OCD in the Geriatric Population

7. Cheryl Wong, M.D.
ACNP/Glaxo Wellcome Fellow
APA/PMRTP Research Fellow

8. Charles Cartwright, M.D.

NAAR/BMS Neuropsychopharmacology of Autism Fellow

9. Sherie Novotny, M.D.

NARSAD Young Investigator Award – "Pharmacological Treatment of Autism: Treating the Dimensions" Mt. Sinai and Seaver Center Research Fellow

10. Alic ia Kaplan, M.D.

Mt. Sinai and Seaver Center Research Fellow

11. Sallie Jo Hadley, M.D.

Mt. Sinai and Seaver Center Research Fellow

12. Stace y Wasserman, M.D.

Mt. Sinai and Seaver Center Research Fellow

13. Alic ia Kaplan, M.D.

Mt. Sinai School of Medicine

14. Evdokia Anagnostou, M.D.

Mt. Sinai and Seaver Center Research Fellow

15. Lat ha Soorya, Ph.D.

Mt. Sinai School of Medicine, NIH Fellow Training In Psychopharmacology and Outcomes Research

16. Ljilja Radulovic, M.D. Mt. Sinai School of Medicine

17. Heather Berlin, Ph.D.Mt. Sinai School of Medicine, NIH FellowTraining In Psychopharmacology and Outcomes Research

18. Jennifer Bartz, Ph.D. Mt. Sinai and Seaver Center Research Fellow

19. Danielle Halperin, PhD NIDA T32 fellow

20. Ting Wang, PhD NIDA T32 fellow

21. Ilana Slaff, MD Seaver/YAI Fellow

Dissertation Committee:

1. Concetta DeCaria - Doctor of Philosophy in Psychology (Neuropsychology) Dissertation: "Psychobiology of Pathological Gambling"

Current Research Activities:

Neuropharmacology/
Neuropsychiatry/
Functional Imaging/
Pharmacological and Psychological Treatment/
of
Autism
Obsessive-Compulsive Disorder
Body Dysmorphic Disorder
Pathological Gambling
Impulsive/Aggressive Personality Disorders
Impulse Control Disorders
OC Related Disorders

Publications

- 1. Nurnberger JI, Simmons-Alling S, Kessler L, Jimerson S, Shreiber J, Hollander E, Tamminga C, Nadi N, Goldstein DS, Gershon ES. Separate mechanisms for behavioral, cardiovascular, and hormonal responses to dextroamphetamine in man. Psychopharmacology, 84:200-204, 1984.
- 2. Hollander E, Mohs RC, Davis KL. Cholinergic approaches to the treatment of Alzheimer's disease. British Medical Bulletin 42:97-100, 1986.
- 3. Hollander E, Mohs RC, Davis KL. Antemortem markers of Alzheimer's disease. Neurobiology of Aging 7:367-387, 1986.
- Davidson M, Kendler KS, Mohs RC, Hollander E, Ryan T, Davis KL. Effect of apomorphine infusion on plasma homovanillic acid in normal subjects. <u>J Psychiatric Research</u> 20(2):131-135, 1986.
- 5. Mohs RC, Hollander E, Haroutunian V, Davidson M, Davis B, Giordani B, Horvath TB, Davis KL. Cholinomimetics in Alzheimer's disease. In: <u>Proceedings of World Congress of Biological Psychiatry</u> 1986.
- 6. Davidson M, Mohs RC, Hollander E, Davis BM, Ryan T, Horvath TB, Davis KL. Physostigmine in patients with Alzheimer's disease. Psychopharmacology Bulletin 22:101-105, 1986.
- 7. Johns CA, Mohs RC, Hollander E, Davis BM, Greenwald BS, Horvath TB, Davis KL. Clinical studies of the cholinergic deficit in Alzheimer's disease. In: International Conference: <a href="https://doi.org/10.1001/john-10.1001/j
- 8. Davis KL, Hollander E, Davidson M, Davis BM, Mohs RC, Horvath TB. Induction of depression with oxotremorine in patient with Alzheimer's disease. <u>American Journal of Psychiatry</u> 144:468-471, 1987.
- Hollander E, Davidson M, Mohs RC, Horvath TB, Davis BM, Zemishlany Z, Davis KL.
 RS 86 in the treatment of Alzheimer's disease: cognitive and biologic effects.
 Biological Psychiatry 22(9):1067-1078, 1987.
- 10. Hollander E, Kapell LA, Mohs RC, Davidson M, Davis BM, Horvath TB, Davis KL. Oral Physostigmine in the treatment of Alzheimer's disease. Geriatric Medicine Today 6(4): 68-76, 1987.
- Davidson M, Mohs RC, Hollander E, Zemishlany Z, Powchik P, Ryan T, Davis KL. Lecithin and piracetam in Alzheimer's disease. <u>Biological Psychiatry</u> 22(1):112-114, 1987. (letter)
- 12. Liebowitz MR, Fyer AJ, Gorman JM, Campeas R, Levin A, Sandberg D, Hollander E, Papp L. Pharmacotherapy of social phobia: a condition distinct from panic attacks. <u>Psychosomatics</u> 28(6):305-308, 1987.
- 13. Hollander E. Non-tartrazine allergy with desipramine. Am J Psychiatry 144(9):1247, 1987. (letter)
- 14. Liebowitz MR, Campeas R, Hollander E. MAOI's: impact on social behavior. <u>Psychiatry</u> Research 22(1):89-90, 1987. (letter)
- Hollander E, Liebowitz MR, Gorman JM. Anxiety disorders. In: <u>American Psychiatric Press Textbook of Psychiatry</u>, Talbott JA, Hales RE, Yudofsky SG, eds. American Psychiatric Press, Washington, D.C., 1988, pp. 443-493.

- 16. Hollander E, Fay M, Cohen B, Campeas R, Gorman JM, Liebowitz MR. Serotonergic and noradrenergic sensitivity in obsessive-compulsive disorder: behavioral findings.

 <u>Am J Psychiatry</u> 145(8):1015-1017, 1988.
- 17. Davidson M, Mohs RC, Kendler KS, Davis B, Johns CA, Hollander E, Horvath TB, Davis KL. Plasma homovanillic acid concentration in schizophrenic patients.

 Biomedicine and Pharmacotherapy (in press).
- 18. Liebowitz MR, Gorman JM, Fyer AJ, Campeas R, Levin AP, Sandberg D, Hollander E, Papp L, Goetz D. Pharmacotherapy of social phobia: an interim report of a placebo controlled comparison of phenelzine and atenolol. <u>J Clin Psychiatry</u> 49(7):252-257, 1988.
- 19. Hollander E, Fay M, Klein DF, Liebowitz MR. Catecholaminergic and monoaminergic effects in obsessive-compulsive disorder. In: Progress in Catecholamine Research, Part C: Clinical Aspects, edited by Belmaker KH, Sandler M, Dahlstrom A. New York: Alan R. Liss, Inc., 1988, pp. 377-383.
- 20. Hollander E, Fay M, Liebowitz MR. Clonidine and clomipramine in obsessive compulsive disorder. Am J Psychiatry 145(3):388-389, 1988. (letter)
- 21. Hollander E, Liebowitz MR. Augmentation of antiobsessional treatment with fenfluramine. Am J Psychiatry 145(10):1314-1315, 1988. (letter)
- 22. Hollander E, Papp L, Campeas R, DeCaria C, Liebowitz MR. More on self mutilation and obsessive compulsive disorder. Can J Psychiatry 33(7):675, 1988. (letter)
- Davidson M, Hollander E, Cohen L, Mohs R, Davis KL: Cholinergic agonists in Alzheimer disease patients. In: <u>Current Research In Alzheimer Therapy</u>, edited by E. Jacobini and R. Becker. Taylor and Francis, Inc., New York, 1988, pp. 333-337.
- 24. Liebowitz MR, Fyer AJ, Gorman JM, Campeas RB, Sandberg DP, Hollander E, Papp LA, Klein DF. Tricyclic therapy of the DSM-III anxiety disorders: a review with implications for further research. <u>J Psychiatry Res</u> 22 (suppl 1):7-31, 1988.
- 25. Fyer AJ, Liebowitz MR, Gorman JM, Campeas R, Levin A, Sandberg D, Fyer M, Hollander E, Papp LA, Goetz D, Klein DF. Effects of clonidine on alprazolam discontinuation in panic patients: a pilot study. <u>J Clin Psychopharmacol</u>, 8(4):270-274, 1988.
- 26. Hollander E, Liebowitz MR, Gorman JM, Cohen B, Fyer AJ, Klein DF. Cortisol and sodium lactate induced panic. <u>Arch Gen Psychiatry</u> 46(2):135-140, 1989.
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- 3. Hollander E, Stein DJ (editors): <u>Impulsivity and Aggression</u>. John Wiley and Sons, Ltd., Sussex, England, 1995.
- 4. Oldham JO, Hollander E, Skodol A (editors): <u>Impulsivity and Compulsivity</u>. American Psychiatric Press, Inc., Washington, DC, 1995.
- 5. Sanchez-Plannell J, Hollander E (editors): <u>Controversies in Dysmorphophobia and Body</u> Dysmorphic <u>Disorder</u>. American Psychiatric Press, Inc., Washington, DC (in press).
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- 8. Simeon D, Hollander E (editors): <u>Self-Injurious Behaviors: Assessment and Treatment.</u>
 American Psychiatric Press, Inc., Washington, DC, 2001.
- 9. Hollander E, Wong CM: <u>Contemporary Diagnosis and Management of Depression, Anxiety, and Obsessive-Compulsive Disorders.</u> Handbooks in Health Care Company, 2000.
- 10. Summers M, with Eric Hollander, M.D.: <u>Everything In Its Place: My Trials and Triumphs With Obsessive Compulsive Disorder</u>. Penguin Putnam, New York, 1999.
- 11. Stein DJ and Hollander E. Anxiety disorders comorbid with depression: social anxiety disorder, post-traumatic stress disorder, generalized anxiety disorder and obsessive-compulsive disorder. Martin Dunitz Ltd., London, England, 2002.
- 12. Hollander E, Simeon D. <u>Concise Guide to Anxiety Disorders</u>. American Psychiatric Publishing Inc., Washington, D.C., 2003.
- 13. Stein DJ, Hollander E (editors): <u>Textbook of Anxiety Disorders</u>. American Psychiatric Publishing, Inc., Washington, DC, 2002.
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- 15. Hollander E (editor): Autism Spectrum Disorders. Marcel Dekker, Inc., New York, 2003.
- 16. Hollander E, Evers M (editor): <u>Contemporary Diagnosis and Management of Mood and Anxiety Disorders</u>. Handbooks In Health Care Company, 2003.
- 17. Hollander E, Bakalar N. <u>Coping with Social Anxiety: The Definitive Guide to Effective Treatment Options</u>. Henry Holt and Company, New York, 2005.
- 18. Hollander E, Stein DJ (editors): <u>Clinical Manual of Impulse Control Disorders</u>. American Psychiatric Publishing, Inc., Washington, DC, 2006.
- 19. Hollander E, Anagnostou E (editors): <u>Clinical Manual for the Treatment of Autism</u>. American Psychiatric Publishing, Inc., Washington, DC, 2007.

20. Hollander E, Simeon D: <u>Anxiety Disorders</u> in <u>Board Prep and Review Guide for Psychiatry</u>. American Psychiatric Publishing, Inc., Washington, DC, 2006.

Exhibit C

CV of Dr. McGinity

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CURRICULUM VITAE

James William McGinity
Professor of Pharmaceutics
College of Pharmacy
The University of Texas at Austin
Austin, Texas 78712-1074

I. Personal

Born in Brisbane, Australia. Citizen of the United States. Married; two children.

II. Education

B. Pharm. degree in December, 1967, from the University of Queensland, Brisbane, Australia. Graduated with the Ph.D. degree in Physical Pharmacy from the University of Iowa in May, 1972. Major Professor was John L. Lach, Ph.D. Short Courses - "Cosmetic Technology" at Columbia University.

III. Positions Held

June 12, 1972 to September 30, 1973 - Research Investigator for E.R. Squibb and Sons, New Brunswick, New Jersey.

October, 1973 to August, 1976 - Associate Professor of Pharmacy at the School of Pharmacy, Texas Southern University, Houston, Texas.

August, 1976 to August, 1979 - Assistant Professor of Pharmacy, College of Pharmacy, University of Texas at Austin, Austin, Texas.

September 1, 1979 to August 31, 1985 - Associate Professor of Pharmacy, College of Pharmacy, University of Texas at Austin, Austin, Texas.

September 1, 1979 to July 2000 - Assistant Director of the Drug Dynamics Institute, University of Texas at Austin, Austin, Texas.

July 2000 to present-Director of the Drug Dynamics Institute, University of Texas at Austin, Austin, Texas.

Appointed to the position of Area Coordinator for the Pharmaceutics Area effective September 1, 1982 and Division Head of Pharmaceutics, January, 1983-August 2007.

September 1, 1985 to present - Professor of Pharmacy, College of Pharmacy, University of Texas at Austin, Austin, Texas.

IV. Graduate and Undergraduate Courses Presented

Product Development, PHR 381D, (Graduate Class) – UT Austin Advanced Manufacturing Pharmacy, PHR 381G (Graduate Class) – UT Austin Advanced Pharmaceutical Processes, PHR 380Q (Graduate Class) – UT Austin Recent Advances in Pharmaceutics, PHR 382R (Graduate Class) – UT Austin Pharmaceutical Dosage Forms, PHR 356C
Pharmaceutical Dosage Forms, PHR 356C
Pharmaceutics I, Lab and Calculations, PHR 133K - UT Austin Basic Manufacturing Pharmacy, PHR 266K - UT Austin Sterile Pharmaceutical Preparations, PHR 357 - UT Austin Pharmaceutics I, PHR 356C and PHR 156P - UT Austin PHR 363, PHR 225K and PHR 380M - UT Austin Lectures were also presented in the following courses—
"Pharmacy Orientation" and "Clinical Toxicology" - TSU

V. Professional Memberships

Society of Cosmetic Chemists American Pharmaceutical Association American Association of Pharmaceutical Scientists (Divisions of Basic Pharmaceutics and Industrial	1972-1973 1969-Present 1985-Present
Pharmaceutical Technology) Rho Chi (Pharmacy Honorary Society)	1970-Present
Phi Lambda Upsilon (Chemistry Honorary Society)	1971-Present
Phi Delta Chi (Pharmacy Professional Fraternity)	1976-Present
Member of the Drug Dynamics Institute,	1974-Present
College of Pharmacy, University of Texas	
Director of the Drug Dynamics Institute	1995-Present
College of Pharmacy, University of Texas	

VI. Current Research Interests

- 1. Several new techniques to microencapsulate drugs using biodegradable polymers have been developed. These formulations are currently under investigation along with the various parameters influencing loading dose, drug release characteristics and physico-chemical properties.
- 2. Topical Drug Delivery Systems: Studies with these systems have been concerned with the physical and chemical factors that influence the <u>in vitro</u> diffusion of drug from each vehicle. Emulsion technology with particular emphasis on micro and multiple emulsion systems.

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- 3. Applications of hot-melt extrusion in the design of pharmaceutical dosage forms.
- 4. Sustained-Release Tablets: Novel controlled-release products have been designed and tested for their release properties <u>in vitro</u>. Mechanisms of drug release are also being investigated.
- 5. Study of the chemical, physical and physico-mechanical properties of polymeric delivery systems including drug delivery by the oral, parenteral and topical routes of administration.
- 6. Film coating technology using aqueous and alcoholic systems. Physicochemical properties of polymers and processing considerations.

VII. Honors and Awards

- 1. Received award (monetary) for the highest grade in Pharmaceutical Chemistry in final undergraduate year, University of Queensland, 1967.
- 2. Recipient of the Lederle Research Award at Texas Southern University for 1974 and 1975.
- 3. Listed in the 1975 awards volume of "Outstanding Educators of America."
- 4. Listed in the 1976 and 1978 volumes of "Who's Who in the South and Southwest."
- 5. Elected to the position of National Secretary for the Basic Pharmaceutics Section of the American Pharmaceutical Association, 1981-1983.
- 6. Listed in the 1978-79 volume of "Personalities of the South."
- 7. Listed in the 1979-80 volume of "Dictionary of International Biography."
- 8. Listed in the first edition of "Personalities of America 1978-80."
- 9. Johnson & Johnson Centennial Chair in Pharmacy, 1985-present
- 10. Fellow of AAPS, 1990.
- 11. North American Editor for European Journal of Pharmaceutics and Biopharmaceutics, 1995.
- 12. Co-Editor for European Journal of Pharmaceutics and Biopharmaceutics, 1996.
- 13. Chairman of the AAPS Fellows Selection Committee, 1999.

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- 14. Nominated for the 1999 Glaxo Wellcome International Achievement Award that is presented by the Royal Pharmaceutical Society of Great Britain.
- 15. Recipient of the 1999 Pharmaceutical Preparation and Particle Design (PPD) Award presented by the Society of Powder Technology Japan.
- 16. Feng Zhang, graduate student under the directorship of Dr. McGinity, received the Outstanding Dissertation Award in the Division of Engineering and Materials Sciences from the University of Texas of Austin. (2000). This is the first time a graduate student in Pharmacy has received this award.
- 17. Recipient of the APSTJ 2004 Takeru & Aya Higuchi Memorial Lectureship that is presented by The Academy of Pharmaceutical Science and Technology Japan, in July 2004 in Kisarazu, Japan.
- 18. Recipient of the 2005 Research Achievement Award in Pharmaceutical Technologies that is presented by the American Association of Pharmaceutical Scientists.
- 19. Recipient of the 2006 *Drug Development and Industrial Pharmacy*Outstanding Paper Award for "Controlled Release of a Poorly Water-Soluble Drug from Hot-Melt Extrudates Containing Acrylic Polymers"
 Yucun Zhu; Navnit H. Shah; A. Waseem Malick; Martin H. Infeld;
 James W. McGinity.

VIII. Committees

- 1. Seminar Chairman and Coordinator for the Squibb Institute for Medical Research (Pharm. R & D) 1972-1973.
- 2. Curriculum Committee 1974 & 1975.
- 3. Library Committee 1975.
- 4. Liaison Officer for the American Journal of Pharmaceutical Education, News Section 1974-1976.
- 5. Admissions Committee 1976, 1977, 1981, 1982.
- 6. Safety Committee 1976-1977.
- 7. Subcommittee on Graduate Student Recruitment 1976-present.

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- 8. Curriculum Committee 1977-1980.
- 9. Ad Hoc Committee on Combined Degree Programs 1977-1978.
- 10. Minority Recruitment Committee (College of Pharmacy Representative on this University committee 1976-1978).
- 11. Member of Steering and Monograph Committee (Academy of Pharmaceutical Sciences) "Codex of Pharmaceutical Excipients" 1977-1980.
- 12. Equipment Committee 1980-1989.
- 13. Academic Performance Committee 1981-1983.
- 14. Administrative and Coordinating Subcommittee 1982-1984.
- 15. Regulations and Scientific Policy Committee, Academy of Pharmaceutical Sciences 1982-1984.
- 16. National Secretary for the Basic Pharmaceutics Section of the American Pharmaceutical Association 1981-1983.
- 17. Program chairman for the 1983 Arden House Conference, a major conference sponsored by the I.P.T. section of the Academy of Pharmaceutical Sciences. Conference title: "Microparticulate Drug Delivery Systems."
- 18. UT College of Pharmacy Representative to "Pharmat" 1981-1982.
- 19. Member of IIPC 1980-1985.
- 20. Equipment Committee 1980-present. Committee Chairman, 1988-present
- 21. Program Committee for the Basic Pharmaceutics Section of the APhA Academy of Pharmaceutical Sciences Midwest Regional meetings
- 22. Program Committee member of the Pharmaceutical Technology Section of the AAPS annual meetings 1990 & 1991.
- 23. Member of AAPS Fellows Selection Committee, 1995-1998.
- 24. Member of Intellectual Property Committee, The University of Texas at Austin, 1994-2003.
- 25. Member of the U.S.P. committee on polymeric excipients. 1995-1997.
- 26. Chairman of the space committee, College of Pharmacy, The University of Texas at Austin, 1995-present.

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- 27. Member of faculty development committee, College of Pharmacy, The University of Texas at Austin. 1995-present.
- 28. Chairman of Self Study Subcommittee on College Resources, 1996-97
- 29. Chairman of AAPS Fellows Selection Committee, 1999.
- 30. Member of the PDD Research Achievement Award Selection Committee, 1999.
- 31. Member of the HØst Madsen Award Selection Committee for the International Pharmaceutical Association. The award is made available by the Danish Pharmaceutical Association to an eminent pharmaceutical scientist, 1999.
- 32. Member of the search committee for the new Director of Intellectual Property. 2003
- 33. Member of AAPS PharmSciTech Oustanding Publication award, member of the committee 2003.
- 34. Member of the AAPS Books Program Review Team 2003.
- 35. Member, AAPS Pharmaceutical Technology Education Committee, 2004-2005.
- 36. Member of the Editorial Board for *The Journal of Pharmaceutical Sciences* (January 2005-December 2007).

IX. Consultantships

List available on request.

X. International Presentations

- 1. Third International Symposium on Microencapsulation, Tokyo, Japan. September, 1976.
- 2. First through Fifth International Conferences on Pharmaceutical Technology, (APGI) Paris, France. 1977, 1980, 1983, 1986 & 1989.
- 3. First International Conference on Powder Technology and Pharmacy, Basel, Switzerland. June, 1978.

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- 4. Fourth International Symposium on Microencapsulation, Miami Beach, Florida, U.S.A. March, 1979.
- 5. First British Pharmaceutical Technology Conference, London, England. April, 1980.
- 6. Australian Pharmaceutical Science Conference and the Annual Meeting of the Australia and New Zealand Association for the Advancement of Science, Adelaide, Australia. May, 1980. Royal Australian Chemical Institute, Sydney, Australia. May, 1980.
- 7. International Symposium on Powder Technology, Kyoto, Japan. September, 1981.
- 8. Second British Pharmaceutical Technology Conference, London, England. April, 1982.
- 9. Twenty-second Annual International Industrial Pharmacy Conference, Texas, U.S.A. February, 1983.
- 10. Fourth British Pharmaceutical Technology Conference, Edinburgh, Scotland. April, 1984 (Member of International Review Board).
- 11. Rohm Pharma Co., Darmstadt, West Germany. 1984, 1986, 1987, 1988, 1989, 1990, & 1991.
- 12. Eudragit Symposium, Rohm Pharma Co., Darmstadt, West Germany. May, 1985.
- 13. Synthelabo Corp., Paris, France, June, 1985.
- 14. Kiel University, Kiel, West Germany, February, 1990.
- 15. Second World Congress on Particle Technology, Kyoto, Japan, September 1990.
- 16. International Conference on Aqueous Polymeric Coating Systems and Related Techniques, Gifu, Japan, September 1990.
- 17. SmithKline Beecham Laboratories, Worthing, England, Short Course "Compaction Technology", April, 1991.
- 18. "Eudragit Symposium", Tokyo & Osaka, Japan, November, 1992.
- 19. "Polymeric Dispersions for Aqueous Film Coating: Physical-Chemical Properties and Processing Considerations", presented at the symposium "Advances in Delivery of Therapeutic and Diagnostic Agents", Sydney, Australia, December 1992.

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- 20. The 12th Pharmaceutical Technology Conference, Elsinore, Denmark, March, 1993.
- 21. 9th Annual Microencapsulation Conference, Ankara, Turkey, September 1993.
- 22. 13th Pharmaceutical Technology Conference, Strasbourg, France, April 1994.
- 23. 14th Pharmaceutical Technology Conference, Barcelona, Spain, April 1995.
- 24. 1st World Meeting on Pharmaceutics, Budapest, Hungary, May 1995.
- 25. 10th International Symposium on Microencapsulation, Austin, Texas, September 1995, Chairman
- 26. APV Conference, Mainz, Germany, March '96.
- 27. Microencapsulation Mini-Symposium, St. Petersburg, Russia, September '96.
- 28. International Biotechnology Meeting, George R. Brown Convention Center, Houston, TX, June '97.
- 29. Particulate Powder Design Award Symposium, Hamamatsu, Japan, October '99.
- 30. APV/APGI 9th International Conference on Pharmaceutical Technology, Berlin, Germany, April 2000.
- 31. "Dry Powder Coating: A Novel Technique for Film Coating Solid Substrates", 29th Conference on Pharmaceutical Technology (sponsored by The Academy of Pharmaceutical Science and Technology, Japan), Kisarazu, Japan, July 2004
- 32. "Melt Extrusion and Controlled Release", 41st Annual Pharmaceutical Technologies Arden Conference-Oral Controlled Release Development and Technology, AAPS, West Point, NY, January 2006.
- 33. "Influence of Processing on the Properties of Pharmaceutical Dosage Forms Containing Acrylic Polymers: Hot-Melt Extrusion or Film Coating", Rohm Pharma, Darmstadt, Germany, March 2006.
- 34. "Curing of Eudragit RL and RS Coatings", "Thermal Processing of Pharmaceutical Powders", "Microencapsulation Technology", "Dry Powder Coating: A Novel Technique for Film Coating Solid Substrates", "Pharmaceutical Patents", "Formulation Design—Application of

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Principles of Materials Science", lectures presented at the University of Navarro, College of Pharmacy, Navarro, Spain, May 15-June 3, 2006.

- 35. "Thermal Processing of Pharmaceutical Powders" presented at Astellas, Shizuoka, Japan, July 17, 2006.
- 36. "Thermal Processing of Pharmaceutical Powders" presented at Dainippon Sumitomo Pharm, in Osaka, Japan, July 18, 2006.
- 37. "Pharmaceutical Patents" presented at Aichi Gakuin University, Nagoya, Japan, July 2006.
- 38. "Physicochemical Factors Influencing Drug Release From Solid Dosage Forms Film Coated by Either a Wet or a Dry Process" presented at The 4th New Pharmaceutical Technology and Engineering Conference, Tokyo, Japan, July 20, 2006.
- 39. "Physical and Chemical Properties of Melt Extruded Polymeric Drug Delivery Systems", 1st International Symposium on Hot Melt Extrusion, March 21-22, 2007, DeGussa, Frankfurt, Germany.
- 40. "Novel Approaches to Prevent Physical Aging of Acrylic Polymers", 8th EUDRAGIT[®] Workshop, April 10-11, 2007, DeGussa, New Brunswick, NJ.
- 41. "Physical and Chemical Properties of Melt Extruded Polymeric Drug Delivery Systems", 2nd International Symposium on Hot Melt Extrusion, Nuremberg, Germany, September 2007.
- 42. "Factors Influencing the Selection of Components and Processing Equipment for Pharmaceutical Applications of Hot Melt Extrusion" APV Conference, Ludwigschafen, Germany, March 2008.

XI. Referee for the Following Journals

- 1. Journal of Pharmaceutical Sciences
- 2. Science
- 3. Pharmacology Biochemistry and Behavior
- 4. International Journal of Pharmaceutics

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- 5. <u>Journal of Microencapsulation</u> (Member of International Board of Editors)
- 6. Pharmaceutical Research
- 7. Journal of Membrane Science
- 8. Life Sciences
- 9. <u>S.T.P. Pharma Sciences</u> (France) (Member of Editorial Board)
- 10. Sciences Techniques et Pratiques Pharmaceuticques (Fr.)
- 11. Journal of Controlled Release
- 12. European Journal of Pharmaceutics and Biopharmaceutics USA Editor
- 13. International Journal of Pharmaceutical Compounding
- 14. <u>Drug Development and Industrial Pharmacy</u> (Member of Editorial Board)
- 15. <u>Pharmaceutical Development and Technology</u> (Member of Editorial Board)
- 16. <u>Drug Delivery Technology</u> (Member of Editorial Advisory Board)
- 17. <u>European Journal of Pharmaceutics</u> (Member of Editorial Board)
- 18. Journal of Pharmacy and Pharmacology
- 19. <u>European Journal of Pharmaceutical Sciences</u> (Member of Editorial Board)
- 20. <u>Tablets and Capsules Magazine</u> (Member of Editorial Advisory Board 2003)
- 21. Current Drug Delivery
- 22. AAPS PharmSci Tech
- 23. Biomaterials
- 24. <u>Journal of Applied Polymer Science</u>
- 25. Journal of Drug Delivery Science and Technology

XII. Personnel Supervised

- 1. Michael R. Harris, Ph.D. (May, 1981) Director, Warner Lambert Corp., Morris Plains, New Jersey.
- 2. George W. Cuff, Ph.D. (May, 1982) Senior Research Scientist, Eli Lilly Co., Indianapolis, Indiana.
- 3. Janet C. Walkow, Ph.D. (August, 1982) Manager, Rorer Pharmaceuticals, Pennsylvania
- 4. Chi-Tze Ku, M.S. (May, 1983) Research Chemist, Bristol Myers Squibb, New Brunswick, N.J.
- 5. Juliette Castillo, M.S. (May, 1983) Lecturer, University of Honduras.
- 6. Professor N.T. Naidoo, Ph.D. (1981-1982) Post-doctoral Research Scholar, Rhodes University, Grahamstown, South Africa.
- 7. Philippe Maincent, Ph.D. (1981-1983) Post-doctoral Research Fellow from the University of Paris, SUD, France. Presently Professor, Nancy University, France.
- 8. Masaki Yamamoto (1982-1983) Visiting Scientist, Takeda Chemical Industries, Osaka, Japan.
- 9. Kenzo Ichizuka (1983-1984) Takeda Chemical Industries, Osaka, Japan, Visiting Scientist.
- 10. Claud G. Cameron, Ph.D. (May, 1986) Watson Laboratories, Corona, CA.
- 11. Robert O. Williams, III, Ph.D. (Dec., 1986) Associate Professor, College of Pharmacy, The University of Texas at Austin, Austin, Texas.
- 12. Steven M. Liebowitz, Ph.D. (1986) Visiting Scientist, Senior Research Scientist, Schering Corp., Kenilworth, NJ
- 13. Roland Bodmeier, Ph.D. (Dec., 1986) Professor, University of Berlin, Berlin, Germany.
- 14. Kuei-Tu Chang, Ph.D. (Dec. 1986) Senior Research Director, Rexall Sundown, Boca Raton, Florida.
- 15. Rafael E. Sarabia, Ph.D., (1985-86) VP, Research & Development, Cima Laboratories, Eden Prairie, Minnesota.

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- 16. George Woo, Ph.D. (May 1988) Research Scientist, Westwood Pharmaceuticals, New York.
- 17. Susan Ashley, Ph.D. (May 1988) Research Scientist, Merck Sharp & Dohme, West Point, PA.
- 18. Jay Thiele, Ph.D. (Dec., 1988) Director of Process Development, Genta Inc., San Diego, CA.
- 19. Mark Schulze, Ph.D., (Dec., 1989) Research Scientist, Glaxo, Inc., North Carolina
- 20. Mark Coffin, Ph.D. (Dec. 1990) Research Scientist, Glaxo, Inc., North Carolina
- 21. Michelle Jenquin, Ph.D., (Dec., 1990) Research Scientist, Rhone-Poulenc Rorer Pharmaceuticals, Horsham, Pennsylvania
- 22. Motokazu Iwata, (1990-91) Visiting Scientist, Dainippon Corp., Osaka, Japan
- 23. Marcelo Omelczuk, Ph.D., (Dec. 1991) Research Scientist, Sandoz Inc., East Hanover, N.J.
- 24. Sakae Obara, Ph.D., (1992-93) Visiting Scientist, Shin-Etsu Chemical Co., Ltd., Tokyo, Japan
- 25. Jose Gutierrez-Rocca, Ph.D. (May 1993) Professor at University of South Miami, Florida
- 26. Steven E. Frisbee, Ph.D., (Dec. 1994), Senior Research Scientist, Biovail Technologies, Ltd., Chantilly, Virginia.
- 27. Carolyn Aitken Nichol, Ph.D., Postdoctoral Fellow, (1994-1995), Assistant Professor, M.D. Anderson Cancer Center, Houston, Texas.
- 28. Unchallee Kositprapa, Ph.D., Research Scientist, (1996) Cima Laboratories, Brooklyn Park, Minnesota.
- 29. Julia Schulze, Visiting Scientist, (1997-1998), University of Berlin, Berlin, Germany.
- 30. Stephan Promeluk, (1997) Visiting Scientist, Germany.
- 31. Chen-Chao Wang, Ph.D., Senior Scientist, (1997) Therics Inc., Princeton, New Jersey.
- 32. Linda Felton, Ph.D., Assistant Professor, (1997) University of New Mexico, Albuquerque, New Mexico.

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- 33. Maria Frohoff Hülsmann, Visiting Scientist (1997), Heinrich-Heine-Universität, Dusseldorf, Germany.
- 34. Stefanie Bendels, Visiting Scientist, (1997), University of Berlin, Berlin, Germany.
- 35. Patrick O'Donnell, Ph.D., Research Scientist, (1997), Ligand Pharmaceuticals, San Diego, California.
- 36. Olaf Zindler, Visiting, Scientist (1998-1999), University of Berlin, Berlin, Germany.
- 37. Chuanbin Wu, Ph.D., (1999) Manager, Research & Development, Watson Foods Co., Inc, New Haven, Connecticut.
- 38. Feng Zhang, Ph.D., Research Scientist, (1999), PharmaForm L.L.C., Dallas, Texas.
- 39. Christelle Anquez, Visiting Scientist, (1999), University of Nancy, Nancy, France.
- 40. Toru Maejima, Visiting Scientist, (1999), Tanabe Seiyaki Co. Ltd, Japan.
- 41. Motonori Kidokoro, Visiting Scientist, (1999), Daiichi Pharmaceutical Co., Ltd., Japan.
- 42. Karl Wagner, Ph.D., Visiting Scientist, (2000), Eberhard-Karls-Universität Tübingen, Tübingen, Germany.
- 43. Michael A. Repka, Ph.D., (2000), Assistant Professor, University of Mississippi, Oxford, Mississippi.
- 44. Eva Gonzalez, Visiting Scientist (2000), Universidad de Santiago de Compostela, Santiago de Compostela, Spain.
- 45. Britta Schroeder, Visiting Scientist (2001-02), Freie Universität, Berlin, Germany.
- 46. Yucun Zhu, Ph.D. (2002), Research Scientist, KOS Pharmaceuticals, Florida.
- 47. L. Diane Bruce, Ph.D. (2002), Research Scientist, Quintilles, Kansas City, Kansas.
- 48. John J. Koleng, Ph.D. (2002), Research Scientist, PharmaForm, L.L.C., Dallas, Texas.

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- 49. Caroline Dietzche, Visiting Scientist, (2002), Freie Universität, Berlin, Germany.
- 50. Dorothea Sauer, Visiting Scientist. (2002), Freie Universitat, Berlin, Germany.
- 51. Anke Fredersdorf, Visiting Scientist, (2003-2003), Freie Universitat, Berlin, Germany.
- 52. Michael Crowley, Ph.D. (2003), Research Scientist, PharmaForm, L.L.C.., Dallas, Texas.
- 53. Matteo Cerea, Visiting Scientist, (2002-2003), University of Milan, Milan, Italy.
- 54. Kevin Kiehm, Visiting Scientist (2003), Goethe University, Frankfurt, Germany.
- 55. Anke Reidel, Visiting Scientist (2003), Leipzig Universitat, Leipzig, Germany.
- 56. Mamoru Fukuda, Visiting Scientist (2003-2005), Kyorin Pharmaceutical Company, Japan.
- 57. Hiroto Onishi, Visiting Scientist (2003-2004), Hoshi University, Japan.
- 58. Hiroto Bando, Visiting Scientist (2004-2005), Takeda Chemical Industries, Inc, Japan.
- 59. Weijia Zheng, Ph.D. (2004), Research Scientist, Novartis, Cambridge, Massachusetts.
- 60. Christopher Young, Ph.D. (2004), Research Scientist, Vertex Pharmaceuticals, Boston, Massachusetts.
- 61. Sandra Schilling, Visiting Scientist (2004-2005), Freie Universitat, Berlin.
- 62. Gavin Andrews, Ph.D., Visiting Scientist (2005), Queen's University of Belfast, U.K.
- 63. Doreen Stimpel, Visiting Scientist (2006), Freie Universitat-Berlin, Germany.
- 64. Stephanie Bosselmann, Visiting Scientist (2006), Freie Universitat-Berlin, Germany.
- 65. Johan Unga, Visiting Scientist (2006), Chalmers University of Technology, Goteborg, Sweden.

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- 66. Claudia Tessman, Visiting Scientist (2006-2007), Freie Universitat-Berlin, Germany.
- 67. Dave Miller, Ph.D. (2007), Research Scientist, Hoffman LaRoche, Nutley, NJ.
- 68. Shawn Kucera, Ph.D. (2007), Senior Research Scientist, Evonik/DeGussa, Piscataway, NJ.
- 69. Caroline Dietzsch Bruce, Ph.D. (2008), Research Scientist, PharmaForm LLC, Austin, TX.
- 70. Dorothea Sauer, Ph.D. (2008), Research Scientist, Abbott Laboratories, Chicago, IL.
- 71. Lonique Coots, (2008), Master's of Science in Pharmaceutics.

Students Currently Being Supervised

James DiNunzio, Ph.D. Candidate Justin Hughey, Ph.D. Candidate Sandra Schilling, Ph.D. Candidate Alan Watts, Ph.D. Candidate

XIII. Publications

- 1. J.W. McGinity, J.A. Hill and A.L. La Via, "Influence of Peroxide Impurities in Polyethylene Glycols on Drug Stability," <u>Journal of Pharmaceutical Sciences</u>, 64, 356-357 (1975).
- 2. J.W. McGinity, A.B. Combs and A.N. Martin, "An Improved Method for Microencapsulation of Soluble Pharmaceuticals," <u>Journal of Pharmaceutical Sciences</u>, 64, 889-890 (1975).
- 3. J.W. McGinity and R.L. Brown, "Stabilizing Effect of Inorganic Phosphate Salts on Antibiotic-Steroid Ophthalmic Preparations," <u>Journal of Pharmaceutical Sciences</u>, 64, 1566-1568 (1975).
- 4. J.W. McGinity and J.A. Hill, "Influence of Monovalent and Divalent Electrolytes on Sorption of Neomycin Sulfate to Attapulgite and

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- Montmorillonite Clays," <u>Journal of Pharmaceutical Sciences</u>, 64, 1566-1568 (1975).
- 5. J.W. McGinity, D.D. Maness and G.J. Yakatan, "The Influence of Various Dispersion Methods on the Rate of Dissolution of Sulfabenzamide," <u>Drug</u> Development Communications, 1(5), 369-387 (1974-1975).
- 6. J.W. McGinity and J.L. Lach, "<u>In Vitro</u> Adsorption Studies of Various Pharmaceuticals to Montmorillonite," <u>Journal of Pharmaceutical Sciences</u>, 65, 896-902 (1976).
- 7. J.W. McGinity, T.R. Patel, A.H. Naqvi and J.A. Hill, "Implications of Peroxide Formation in Lotion and Ointment Dosage Forms Containing Polyethylene Glycols," <u>Drug Development Communications</u>, 2, 505-519 (1976).
- 8. J.W. McGinity and J.L. Lach, "Sustained-Release Applications of Montomorillonite Interactions with Amphetamine," <u>Journal of Pharmaceutical Sciences</u>, 66, 63-66 (1977).
- 9. J.W. McGinity and C.S. Mehta, "Chronic Administration of Cyanide: Urinary Excretion of Thiocyanate in Male and Female Rats," <u>Acta Pharmacol.</u> et Toxicol., 41, 49-52 (1977).
- 10. M.J. Akers, R.D. Schoenwald and J.W. McGinity, "Practical Aspects of Ophthalmic Drug Development," <u>Drug Development and Industrial Pharmacy</u>, 3, 185-217 (1977).
- 11. T.P. Faulkner, J.W. McGinity, J.H. Hayden, M. Martinez and E.G. Comstock, "Pharmacokinetic Studies on Tolerance to Multiple Doses of Sedative-Hypnotics in a Poly-Drug Abuse Population I. Secobarbital, "J. Clin. Pharm. and Therap., 23, 36-46 (1978).
- 12. J.W. McGinity, "Solving Dissolution Problems with Solid Dispersions," <u>Journal of Pharmaceutical Technology</u>, 2, (3), 50-54 (1978).
- 13. C.K. Erickson, K.I. Koch, C.S. Mehta and J.W. McGinity, "Chronic Alcohol Release: Subcutaneous Silastic Implants in Mice," <u>Science</u>, 199, 1457-1459 (1978).
- 14. C.K. Erickson, K.I. Koch, C.S. Mehta and J.W. McGinity, "Chronic Dependence with a Sustained Ethanol Release Implant in Mice," <u>Life Science</u>, 22, 1745-1754 (1978).
- 15. J.W. McGinity and C.S. Mehta, "Preparation and Evaluation of a Sustained Morphine Delivery System in Rats," <u>Pharmacol. Biochem.</u> Behav., 9, 705-708 (1978).

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- 16. J. Newburger, S. Hayes, M. Ruff and J.W. McGinity, "Determination of Sodium Chloride Equivalents by Osmometry," <u>Drug Development and Industrial Pharmacy</u>, 5(2), 93-105 (1979).
- 17. J.W. McGinity, L.A. Hunke and A.B. Combs, "Effect of Water Soluble Carriers on the Release of Morphine Sulfate from a Silicone Polymer," <u>Journal of Pharmaceutical Sciences</u>, 68, 662-664 (1979).
- 18. T.P. Faulkner, J.W. McGinity et al., "Pharmacokinetic Studies on Tolerance to Multiple Doses of Sedative-Hypnotics in a Poly-Drug Abuse Population II. Secobarbital Amobarbital," <u>Journal of Clinical Pharmacology</u>, 19, 605-616 (1979).
- 19. J.W. McGinity, A.B. Combs and A. Martin, "<u>In Vitro</u> Release Characteristics of Sodium Sulfathiazole from Formalin-Treated Nylon Gelatin Microcapsules," In <u>Microencapsulation</u>, T. Kondo, Ed., Techno Inc. Publishing Co., Tokyo, Japan, 57-77 (1979).
- 20. J.W. McGinity and M.R. Harris, "Increasing Dissolution Rates of Poorly Soluble Drugs by Adsorption to Montmorillonite," <u>Drug Development and Industrial Pharmacy</u>, 6, 35-48 (1980).
- 21. J.W. McGinity and M.R. Harris, "Influence of a Montmorillonite Clay on the Properties of Griseofulvin Tablets," <u>Drug Development and Industrial Pharmacy</u>, 6, 49-59 (1980).
- 22. W.H. Riffee, R.E. Wilcox, J.A. Anderson and J.W. McGinity, "Silastic Pellets for Sustained Delivery of Morphine in Mice", <u>Journal of Pharmaceutical Sciences</u>, 69, 980-982 (1980).
- 23. J.W. McGinity and M.R. Harris, "Optimization of Slow-Relese Tablet Formulations Containing Montmorillonite I. Properties of Tablets", <u>Drug Development and Industrial Pharmacy</u>, 6(4), 339-410 (1980).
- 24. C.K. Erickson, K.I. Koch and J.W. McGinity, "Subcutaneous Silastic Implants: Maintenence of High Blood Ethanol Levels in Rats Drinking a Liquid Diet," <u>Pharmacology & Biochemistry Behavior</u>, 13, 781-786 (1980).
- 25. J.W. McGinity, A. Martin, G.W. Cuff and A.B. Combs, "Influences of Matrixes on Nylon Encapsulated Pharmaceuticals," <u>Journal of Pharmaceutical Sciences</u>, 70 (4), 372-375 (1981).
- 26. J.W. McGinity, S. Stavchansky and A. Martin, "Bioavailability in Tablet Technology," in <u>Pharmaceutical Dosage Forms: Tablets</u>, Vol. 2, H. Liberman and L. Lackman, Editors, M. Dekker, Publisher, Chapter 6, 269-449 (1981).
- 27. J.W. McGinity, G.W. Cuff and A.B. Combs, "Microencapsulation of Pharmaceuticals," <u>Aust. J. Pharm. Sci.</u>, 10, 17-19 (1981).

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- 28. M.J. Miralles, J.W. McGinity and A. Martin, "Combined Water-Soluble Carriers for Coprecipitates of Tolbutamide," <u>Journal of Pharmaceutical</u> Sciences, 71, 302-304 (1982).
- 29. M.R. Harris and J.W. McGinity, "Optimization of Slow-Release Formulations Containing Montmorillonite II. Factors Affecting Drug Release," <u>Drug Development and Industrial Pharmacy</u>, 8(6), 783-793 (1982).
- 30. M.R. Harris and J.W. McGinity, "Optimization of Slow-Release Formulations Containing Montmorillonite III. Mechanism of Release," <u>Drug Development and Industrial Pharmacy</u>, 8(6), 795-809 (1982).
- 31. C.K. Erickson, S.A. Stavchansky, K.I. Koch and J.W. McGinity, "Sustained Release of Nicotine: A New Pharmacological Tool," Pharmacology Biochemistry and Behavior, 17, 183-185 (1982).
- 32. J.W. McGinity, C.G. Cameron and G.W. Cuff, "Controlled-Release Theophylline Tablet Formulations Containing Acrylic Resins. I. Dissolution Properties of Tablets," <u>Drug Development and Industrial Pharmacy</u>, 9, 57-68 (1983).
- 33. J.W. McGinity, "Drug Delivery Systems," <u>Discovery</u> 8(1), 11-14 (1983).
- 34. G.W. Cuff, A.B. Combs and J.W. McGinity, "Effect of Formulation Factors on the Matrix pH of Nylon Microcapsules," <u>Journal of Microencapsulation</u>, 1(1) 27-32 (1984).
- 35. J.W. McGinity, P. Maincent, H. Steinfink, "Crystallinity and Dissolution Rate of Tolbutamide Solid Dispersions Prepared by the Melt Method", <u>Journal of Pharmaceutical Sciences.</u> 73, 1441-1444 (1984).
- 36. G.W. Cuff and J.W. McGinity, "Expanded Versatility of Microcapsules Prepared by Interfacial Polymerization," <u>Journal of Microencapsulation</u>, 1(4) 343-347 (1984).
- 37. M.R. Harris, J.B. Schwartz and J.W. McGinity, "Optimization of Slow-Release Tablet Formulation Containing Sodium Sulfathiazole and Montmorillonite Clay," <u>Drug Development and Industrial Pharmacy</u>, 11(5) 1089-1110 (1985).
- 38. J.W. McGinity and G.W. Cuff, "Nylon Encapsulated Pharmaceuticals" in Drug and Enzyme Targeting, Vol. 1, Ed. K.J. Widder and R. Green, Academic Press, Inc., NY, 84-101 (1985).
- 39. J.W. McGinity, Chi-Tze Ku, R. Bodmeier and M.R. Harris, "Dissolution and Uniformity Properties of Ordered Mixes of Micronized Griseofulvin and a Directly Compressible Excipient," <u>Drug Development and Industrial Pharmacy</u>, II(4) 891-900 (1985).

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- 40. J.W. McGinity and M.R. Harris, "Sodium Alginate," <u>Codex of Pharmaceutical Excipients</u>, 257-258 (1986).
- 41. J.W. McGinity and M.R. Harris, and K. Patel, "Carbomer," <u>Codex of Pharmaceutical Excipients</u>, 41-42 (1986).
- 42. J.W. McGinity, M.R. Harris, and R. Dusch, "Alginic Acid," Codex of Pharmaceutical Excipients, 5 (1986).
- 43. C.G. Cameron and J.W. McGinity, "Controlled-Release Theophylline Tablet Formulation Containing Acrylic Resins, II. Combination Resin Formulation" <u>Drug Development and Industrial Pharmacy</u>, 13, 1409-1427 (1987).
- 44. C.G. Cameron and J.W. McGinity, "Controlled-Release Theophylline Tablet Formulations Containing Acrylic Resins. III. Influence of Filler Excipient" <u>Drug Development and Industrial Pharmacy</u>, 13, 303-318 (1987).
- 45. J.C. Walkow and J.W. McGinity, "The Effect of Physicochemical Properties on the <u>In Vitro</u> Diffusion of Drug Through Synthetic Membranes and Pigskin I. Methylsalicylate," <u>International Journal of Pharmaceutics</u>, 35, 91-102 (1987).
- 46. J.C. Walkow and J.W. McGinity, "The Effect of Physicochemical Properties on the <u>In Vitro</u> Diffusion of Drug Through Synthetic Membranes and Pigskin II. Salicylic Acid," <u>International Journal of Pharmaceutics</u>, 35, 103-109 (1987).
- 47. R. Bodmeier and J.W. McGinity, "Polylactic and Microspheres Containing Quinidine Base and Quinidine Sulphate Prepared by the Solvent Evaporation Technique: I. Methods and Morphology," <u>Journal of Microencapsulation</u>, 4, 279-288 (1987).
- 48. R. Bodmeier and J.W. McGinity, "Polylactic and Microspheres Containing Quinidine Base and Quinidine Sulpha Prepared by the Solvent Evaporation Technique: II. Process Parameters Influencing the Preparation of Properties of Microspheres," <u>Journal of Microencapsulation</u>, 4, 289-297 (1987).
- 49. A.A. Fus, R.L. Talbert, and J. W. McGinity, "Fate of Ferrous Sulphate Prescription", <u>The American Journal of Medicine</u>, 83, 386-388 (1987).
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- 155. J.C. DiNunzio, R.O. Williams III, J.W. McGinity, "A Review of Development and Design Technology for Next Generation Dry Powder Inhalers", Drug Delivery Technology, 7:9, 22-34, (2007).

- 156. Sandra U. Schilling, Navnit H. Shah, A. Waseem Malick, Martin H. Infeld and J.W. McGinity, "Citric Acid as a Solid State Plasticizer for Eudragit RS PO", <u>Journal of Pharmacy and Pharmacology</u>, 59:11, 1493-1500 (2007).
- 157. M. Fukuda, D.A. Miller, N.A. Peppas, J.W. McGinity, "Influence Of Sulfobutyl Ether beta-Cyclodextrin (Captisol®) On The Dissolution Properties Of A Poorly Soluble Drug From Extrudates Prepared By Hot-Melt Extrusion", <u>International Journal of Pharmaceutics</u>, 350:1-2, 188-196, (2008).
- 158. S.A. Kucera, D. Stimpel, N.H. Shah, A.W. Malick, M.H. Infeld, J.W. McGinity, "Influence of Fumed Silicon Dioxide on the Stabilization of Eudragit RS/RL 30 D Film-Coated Theophylline Pellets", <u>Pharmaceutical Development and Technology</u>, 13:245-253, (2008).
- 159. G.A. Andrews, D.S. Jones, O.A. Diak. C.P. McCoy. A.B. Watts, J.W. McGinity, "The Manufacture and Characterisation of Hot Melt Extruded Enteric Tablets" <u>European Journal of Pharmaceutics and Biopharmaceutics</u>, 69: 264–273, (2008).
- 160. D.A. Miller, J.C. DiNunzio, W. Yang, J.W. McGinity, R.O. Williams III, "Targeted Intestinal Delivery of Supersaturated Itraconazole for Improved Oral Absorption", Pharmaceutical Research, 25:6, 1450-1459, (2008).
- 161. D.A. Miller, J.C. DiNunzio, W. Yang, J.W. McGinity, R.O. Williams III, "Enhanced In Vivo Absorption of Itraconazole via Stabilization of Supersaturation Following Acidic-to-Neutral pH Transition", <u>Drug Development and Industrial Pharmacy</u>, 34:890-902, (2008)
- 162. Sandra U. Schilling, Caroline D. Bruce, Navnit H. Shah, A. Waseem Malick, and James W. McGinity, "Citric Acid Monohydrate as a Release Modifying Agent in Melt Extruded Matrix Tablets", <u>International Journal</u> of Pharmaceutics, 361, 158-168, (2008).
- 163. J.C. DiNunzio and J.W. McGinity, "Hot Melt Extrusion", back page column, <u>Tablets and Capsules</u>, 6:6, 64, (2008).
- J. DiNunzio, D. Miller, R.O. Williams III, J.W. McGinity, "Formulating Compositions to Achieve Enhanced Oral Bioavailability Through Supersaturation", <u>Drug Delivery Technology</u>, 8:9, 24-33, (2008).
- 165. S. Kucera, C. Tessman, N.H. Shah, A.W. Malick, M.H. Infeld, J.W. McGinity, "The Influence of Ethylcellulose Polymers on the Physical Stability of Theophylline Pellets Coated with Eudragit NE 30D" <u>Journal of Drug Delivery Science and Technology</u>, 18:5, 343-349, (2008).

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- 167. S.A. Kucera, N.H. Shah, A.W. Malick, M.H. Infeld, J.W. McGinity, "Influence of an Acrylic Polymer Blend on the Physical Stability of Film-Coated Theophylline Pellets" <u>AAPS Pharm Sci Tech</u>, in press, September 2008.
- 168. D. Sauer, A. B. Watts, L.B. Coots, W. Zheng, J.W. McGinity, "Influence of polymeric subcoats on the drug release properties of tablets powder-coated with pre-plasticized Eudragit® L 100-55.", <u>International Journal of Pharmaceutics</u>, in press, September 2008.

XIV. Book Chapters:

- 1. J.W. McGinity, A.B. Combs and A. Martin, "<u>In Vitro</u> Release Characteristics of Sodium Sulfathiazole from Formalin-Treated Nylon Gelatin Microcapsules," in *Microencapsulation*, T. Kondo, Ed., Techno Inc. Publishing Co., Tokyo, Japan, pp. 57-77 (1979).
- 2. J.W. McGinity, S. Stavchansky and A. Martin, "Bioavailability in Tablet Technology," in *Pharmaceutical Dosage Forms: Tablets, Vol. 2*, H. Liberman and L. Lachman, Editors, M. Dekker, Publisher, Chapter 6, 269-449 (1981).
- 3. J.W. McGinity and G.W. Cuff, "Nylon Encapsulated Pharmaceuticals" in *Drug and Enzyme Targeting, Vol. 1*, Ed. K.J. Widder and R. Green, Academic Press, Inc., NY, pp. 84-101 (1985).
- 4. Y. Kawashima, H. Takeuchi, T. Handa, W.J. Thiele, D.P. Deen and J.W. McGinity, "Aqueous Based Coatings in Matrix Tablet Formulations" a chapter in *Aqueous Based Coatings in Pharmaceutical Systems*, Ed. J.W. McGinity, Publ., Marcel Dekker Inc. New York, NY, (1988), pp 363-397.
- 5. J.W. McGinity and M.D. Coffin, "Cooling Processes and Congealing", in *Encyclopedia of Pharmaceutical Technology, Vol. 3*, Publ. Marcel Dekker, Inc., New York, New York pp 315-335 (1990).
- 6. J.W. McGinity, "Applications and Physical-Chemical Properties of Aqueous Polymeric Coatings for Drug Delivery Systems" in *Recent*

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- Advances on Aqueous Polymeric Coating Systems and Related Techniques", Ed. Y Kawahima, pp 1-10 (1990).
- 7. J.W. McGinity and S. Stavchansky, "Bioavailability in Tablet Technology" in *Pharmaceutical Dosage Forms: Tablets Vol.* 2, Ed. H Lieberman, pp 349-569 (1990).
- 8. J.W. McGinity, K.T. Chang, and M.O. Omelczuk, "Biodegradable Polymers: Effect of Thermal Treatment on the Physicomechanical and Dissolution Properties of Compacts", in *Pharmaceutical Technology*, Ed. J. Wells and M. Rubinstein, pp 132-141 (1991).
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- 10. P.B. O'Donnell and J.W. McGinity, "Pharmaceutical Applications of Minerals", in *Industrial Minerals and Their Uses: A Handbook & Formulary*, Ed. P.A. Ciullo, Noyes Publications, 401-433 (1996).
- 11. M. Coffin, S. Frisbee, and J.W. McGinity, "Properties of Aqueous Pseudolatex Dispersions of Biodegradable Polymers", chapter in *Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms, 2nd Edition*, Marcel Dekker Inc., (1996).
- 12. P. O'Donnell and J.W. McGinity, "Mechanical Properties of Polymeric Films Prepared from Aqueous Polymeric Dispersions", chapter in *Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms,l 2nd Edition*, Marcel Dekker Inc., (1996).
- 13. Theme Issue on Microparticles and Microcapsules, J.W. McGinity, Editor, *European Journal of Pharmaceutics and Biopharmaceutics*, Vol. 45, No. 1, (January 1998).
- 14. J. Koleng & J.W. McGinity, chapter on Carbomer in *Handbook of Pharmaceutical Excipients, 3rd Edition*, Ed. Arthur H. Kibbe, American Pharmaceutical Association and Pharmaceutical Press, 79-82, (2000).
- 15. M. Repka & J.W. McGinity, chapter on Alginic Acid in *Handbook of Pharmaceutical Excipients, 3rd Edition*, Ed. Arthur H. Kibbe, American Pharmaceutical Association and Pharmaceutical Press, 10-12, (2000).
- 16. J.W. McGinity, J.J. Koleng, M.A. Repka, and F. Zheng, *Hot Melt Extrusion Technology*, chapter in the Volume 19 of the *Encyclopedia of Pharmaceutical Technology*, Marcel Dekker, Ed. J. Swarbrick and J.C. Boylan, pp. 203-226 (2000).

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- 19. J.W. McGinity & F. Zhang, "Melt-Extruded Controlled Release Oral Dosage Forms" chapter in *Pharmaceutical Extrusion Technology*, Volume 133 from Drugs and the Pharmaceutical Sciences series, Ed. I. Ghebre-Sellassie, Marcel Dekker, Chapter 10, pp. 183-208, May 2003.
- 20. D.A. Miller, J.W. McGinity. R.O. Williams III, Book Chapter: "Solid Dispersion Technologies: Improving Oral Drug Therapies", in *Advanced Formulation Design to Optimize Therapeutic Outcomes*, Ed. Williams, Taft and McConville. Informa Healthcare, pp. 451-492, February 2008.
- 21. J.W. McGinity & D. Miller, "Aqueous Polymeric Film Coating", chapter in *Pharmaceutical Dosage Forms: Tablets, 3rd Edition*, Editors Stephen Hoag and Larry Augsberger, pp. 399-457, June 2008.
- 22. P.B. O'Donnell, L.A. Felton, J.W. McGinity, "Mechanical Properties of Polymeric Films Prepared From Aqueous Polymeric Dispersions", *Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms, 3rd Edition*, Eds. Felton & McGinity, Informa Healthcare, Chapter 4, pp. 105-128, January 2008.
- 23. L.A. Felton, J.W. McGinity, "Adhesion of Polymeric Films", *Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms, 3rd Edition*, Eds. Felton & McGinity, Informa Healthcare, Chapter 6, pp. 151-170, January 2008.
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- 25. S. Frisbee, M. Coffin and J.W. McGinity, "Properties of Aqueous Pseudolatex Dispersions of Biodegradable Polymers", *Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms*, 3rd Edition, Eds. Felton & McGinity, Informa Healthcare, Chapter 14, pp. 409-443, January 2008.
- 26. L.A. Felton, S. Kucera, J.W. McGinity, "Physical Aging of Polymeric Film Coats", *Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms*, 3rd Edition, Eds. Felton & McGinity, Informa Healthcare, Chapter 15, pp. 445-474, January 2008.

XV. Patents:

- J.W. McGinity, "Corticosteroid Phosphate Salts/Neomycin Sulfate Ophthalmic",
 <u>U.S. Patent 3,898,330</u> (1975)
 <u>Canadian Patent CA 1031262</u> (1978).
- 2. R. Morrow, W. Kuebker and J.W. McGinity, "Fresh-gard Dental Lubricant Formulations", <u>U.S. Patent 4,537,689</u>, (1985).
- 3. G.W. Cuff and J.W. McGinity, "Improved Method for Preparing Nylon Microcapsules", <u>U.S. Patent 4,518,547</u>, (1985). Foreign patent applications made in West Germany, U.K., and Japan.
- J. Schonfeld and J.W. McGinity, "Color Stabilized Hydrogel Dressing and Process",
 <u>U.S. Patent Number 4,646,730</u>, (1987).
 Canadian Patent CA 1277910,
- Kuei-Tu Chang and J.W. McGinity, "Method for Preparing a Solid Sustained Release Form of a Functionally Active Composition", <u>U.S. Patent Number 5,051,261</u>, (1991). Canadian Patent CA 1334379, (1995).
- 6. J.C. Greco and J.W. McGinity, "Vaginal Progesterone Tablet", U.S. Patent 5,084,277 (1992).
- 7. J.C. Greco and J.W. McGinity, "Progesterone Vaginal Tablet", U.S. Patent 5,116,619, (1992).
- 8. J.W. McGinity and S.L. Ashley, "Delivery of Therapeutic Agents", U.S. Patent 5,227,157, (1993).
- J.W. McGinity and M. Iwata, "Preparation and Uses of Multi-Phase Microspheres", <u>U.S. Patent 5,288,502</u>, (1994).
- J.W. McGinity, R. Bodmeier, B. Oshlack, and M. Chasin, "Aqueous Dispersions of Zein and Preparation Thereof", <u>U.S. Patent 5,324,351</u>, (1994).
- 11. B. Oshlack, J.W. McGinity, R. Bodmeier, M. Chasin, "Controlled Release Coatings Derived from Aqueous Dispersions of Zein", U.S. Patent 5,356,467, (1994).
- 12. J.W. McGinity, T. Gerding, R. Bodmeier, "Stick Formulations for Topical Drug Delivery of Therapeutic Agents and Uses Thereof",

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U.S. Patent 5,597,849 (1997)

- 13. R. Bodmeier, T.G. Gerding, J.W. McGinity, "Stick Formulations for Topical Drug Delivery of Therapeutic Agents and Uses Thereof", U.S. Patent 5,622.993, (1997).
- 14. V. Stella, J.W. McGinity *et al*, "Sulfoalkyl Ether Cyclodextrin Based Solid Pharmaceuticals", U.S. Patent 5,874,418, (1999).
- 15. V. Stella, J.W. McGinity *et al*, "Sulfoalkyl Ether Cyclodextrin Based Controlled Release Solid Pharmaceutical Formulations", <u>U.S. Patent 6,046,177</u>, April 4, (2000) <u>Canadian Patent CA 2289202</u>, May 15, (2005).
- J.R. Robinson and J.W. McGinity, "Effervescent Granules and Methods for Their Preparation", U.S. Patent 6,071,539, June 6, 2000.
- 17. R. Bodmeier and J.W. McGinity, "Method for Improving the Dispersion of Redispersible Polymer Powders", U.S. Patent 6,169,130, January 2, 2001.
- Z. Shaked and J.W. McGinity, "Pharmaceutical Formulation Containing DFMO for the Treatment of Cancer", <u>U.S. Patent 6,277,411</u>, August 21, 2001.
- 19. M.A. Repka, S.L. Repka and J.W. McGinity, "Bioadhesive Hot-Melt Extruded Film for Topical and Mucosal Adhesion Applications and Drug Delivery and Process for Preparation Thereof", U.S. Patent 6,375,963, April 23, 2002.
- 20. F. Zhang and J. W. McGinity, "Hot-Melt Extrudable Pharmaceutical Formulation"
 U.S. Patent 6,488,963, December 3, 2002.
- J.R. Robinson and J.W. McGinity, "Effervescent Granules and Methods for Their Preparation"
 U.S. Patent 6,488,961, December 3, 2002.
- J.R. Robinson, P. Delmas, J.W. McGinity, "Effervescent Granules and Methods for Their Preparation"
 U.S. Patent 6,649,186, November 18, 2003.
- J.R. Robinson and J.W. McGinity, "Delivery System for Omeprazole and Its Salts",
 U.S. Patent 6,749,867, June 15, 2004

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24. Dave A. Miller, Jason T. McConville, James W. McGinity, Robert O. Williams III, "Stabilized HME Composition with Small Drug Particles" European Patent Application #WO2007001451, April 2007.

XVI. Books:

- 1. J.W. McGinity, ed. <u>Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms</u>, Marcel Dekker publ., (1989).
- 2. J.W. McGinity, ed. <u>Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms</u>, 2nd Edition, Marcel Dekker Inc., (1996).
- 3. J.W. McGinity and L. Felton, ed., <u>Aqueous Polymeric Coatings for Pharmaceutical Dosage Forms</u>, 3rd Edition, Informa Healthcare, January (2008).

XVII: Book Reviews:

- 1. "Microencapsulation," J.R. Nixon, Editor, Marcel Dekker, Publisher, New York, N.Y. (1976). J. Pharm. Sci., 66, 148 (1977).
- 2. "Controlled-Release of Bioactive Materials," R. Baker, Editor, Academic Press, New York, N.Y. (1980). J. Pharm. Sci., 70, 837 (1981).
- 3. "Drug Stability: Principles and Practices", J.T. Carstensen, Editor, Marcel Dekker, Publisher, New York, N.Y. (1990). J. Pharm. Sci., 80, 98 (1991).
- 4. "Handbook of Pharmaceutical Granulation Technology", Second Edition, D.M. Parikh, Taylor and Francis, Boca Raton, FL 2005, Hardback, 656 pages, ISBN: 0824726472, <u>Drug Development and Industrial Pharmacy</u>, 33,1-2 (2007).

11/21/2008

Exhibit D

CV of Dr. Sawchuk

RONALD J. SAWCHUK

PERSONAL DATA

Department of Pharmaceutics Present Address:

College of Pharmacy

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University of Minnesota 308 Harvard Street S.E. Minneapolis, MN 55455

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Home Address: 14934 Pixie Point Circle SE

Prior Lake, MN 55372

Telephone: (952) 226-6507

May 29, 1940, Toronto, Ontario, Canada Born:

Married, three children Marital Status: Dual: U.S. and Canadian Citizenship:

EDUCATION

1959	(High School)	Oakwood Collegiate Institute, Toronto
		Secondary School Grade XIII)
1963	B.Sc. Phm.	University of Toronto, Toronto
		Ontario College of Pharmacy Licentiate No. 10748
1966	M. Sc. Phm.	University of Toronto, Toronto
1972	Ph.D.	University of California, San Francisco
		Pharmaceutical Chemistry (Pharmacokinetics)

PROFESSIONAL AND ACADEMIC EXPERIENCE

1963 - 1965	Teaching Assistant, University of Toronto
1966	Community Pharmacist (part-time), Toronto
1966 - 1968	Teaching Assistant, University of California
1971 - 1972	Instructor in Pharmaceutics, University of Minnesota
1972 - 1977	Assistant Professor of Pharmaceutics, University of Minnesota
1977 -1983	Associate Professor of Pharmaceutics, University of Minnesota
1974 - 1982	Associate Director, Clinical Pharmacokinetics Laboratory, U of Minnesota
1982 - 1995	Director, Clinical Pharmacokinetics Laboratory, College of Pharmacy, U of Minnesota
1983 - present	Professor of Pharmaceutics, University of Minnesota
1983 - 1989	Director of Graduate Studies in Pharmaceutics, University of Minnesota
1983 - 1986	Acting Head, Department of Pharmaceutics, University of Minnesota
1984 (summer)	Quarter Leave, Sandoz Pharma, Pharmacokinetics and Drug Metabolism Dept.,
	Basel, Switzerland (M. Lemaire)
1991 - 1994	Director of Graduate Studies in Pharmaceutics, University of Minnesota
1992 (Summer)	Quarter Leave, Sandoz Pharma, Drug Safety, Basel, Switzerland (W. Niederberger)
1996 - 1999	Member, Board of Directors, Century Mortar Club
1997 (Spring)	Semi-Quarter Leave, Toyama Medical and Pharmaceutical University, Japan (H. Sato)
1997 (Summer)	Semi-Quarter Leave, Novartis AG, PKDM, Basel, Switzerland (J. Vonderscher)
1998 - 1999	Head, Department of Pharmaceutics, University of Minnesota
2001 (Summer)	Faculty Development Leave, Novartis AG, PKDM, Basel, Switzerland (M. Lemaire)

CURRENT PROFESSIONAL RESPONSIBILITIES

1972 - present	Member, Graduate Program in Pharmacutics, University of Minnesota
1983 - present	Professor of Pharmaceutics, University of Minnesota
1982 - present	Consultant to the pharmaceutical industry
1995 - present	Director, Bioanalytic and Pharmacokinetic Services, University of Minnesota
1995 - present	Editorial Board, Saudi Pharmaceutical Journal
1996 - 2007	Editorial Board, Journal of Pharmaceutical Sciences
1996 - present	Member, Graduate Program in Neurosciences, University of Minnesota
2001 - present	Member, Graduate Program in Experimental and Clinical Pharmacology, U of M
2002 - present	Member, Graduate Program in Social, Administrative and Clinical Pharmacy, U of M
2008 - present	Editorial Advisory Board, AAPS Journal
2009 - present	Editorial Board, Xenobiotica

OTHER PROFESSIONAL ACTIVITIES AND RESPONSIBILITIES

Prepared two videotapes on "Pharmacokinetics" for undergraduate instruction

Co-editor of a book with James Blanchard, Ph.D. and B.B. Brodie, Ph.D., entitled "Principles and Perspectives in Drug Bioavailability." S. Karger, Publisher, 1979

Assistant Director, Clinical Pharmacokinetics Laboratory, 1974-82

Consultant in the Establishment and Implementation of the Drug Quality Assurance Program, United Hospitals, St. Luke's Division, St. Paul, 1975

Participant in Critical Incidents Workshop, PDI - College of Pharmacy, 1977

Assessor in the Pharmacy Assessment Exercises, 1978

Coordinator for Continuing Education in Pharmacy, TV Series 1978, 1980

Expert, Bureau of Drugs and Biologics, Food and Drug Administration, 1982-84

Screening Committee, Abstracts, Basic Pharmaceutics Section, APS, APhA, 1981

Review of Grants, Medical Research Council (Canada) 1980-86

Review of Grants, British Columbia Health Care Foundation, 1981-84

Advisory Consultant, Site Visit Team NIH (NINCDS) Yale University School of Medicine, October 1979

Member, Site Visit Team NIH (NINCDS) University of Utah School of Medicine, January 1983

Member, Special Pharmacology Study Section NIH, April-June 1988

Review of Grants, Idaho State Board of Education, 1989-91

Review of Grants, Greater Minnesota Corporation, 1990-91

Organizer and Symposium Co-Chair, "Microdialysis in Drug Metabolism and Disposition Studies", for the Annual AAPS Meeting, San Antonio TX, 1992

Symposium Co-Chair, "Kinetic and Dynamic Challenges of the 90's", for the Annual AAPS Meeting, San Diego, CA, 1994

Organizing Committee Member for the NATO Advanced Study Institute, "Pharmacokinetics: From Theory to Practice", Erice, Italy, April 5-16, 1994

Co-organizer and Participating Instructor, "Pharmacokinetics for the Pharmacist and Pharmaceutical Scientist" University of Milan, Varese, September 10 -15, 1995.

Member, Board of Directors, Century Mortar Club, 1996-present.

National Advisory Committee, FAMU RCMI Program, Tallahasse, FL 1996-present

Co-organizer and Participating Instructor, "Pharmacokinetics for the Biomedical and Pharmaceutical Scientist" University of Milan, Varese, September 7 -12, 1997.

Scientific Advisory Committee, 1st Symposium on Microdialysis and Pharmacokinetics, Leiden, The Netherlands April 1998

Organizer and Participating Instructor, "Pharmacokinetics for the Biomedical and Pharmaceutical Scientist" University of Malta, Msida, September 6 -15, 1998.

Founder, Microdialysis Focus Group, American Association of Pharmaceutical Scientists, 1998.

Scientific Advisory Committee, 2nd International Symposium on Microdialysis in Drug Research and Development, Stockholm, Sweden, June 2000

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Chair, Microdialysis Focus Group, American Association of Pharmaceutical Scientists, 1998-2000.

Co-Chair, Organizing Committee, 3rd International Symposium on Microdialysis in Drug Research and Development, Minneapolis, MN, USA, June 2002

Visiting Professor, Guilin Medical College, Guilin PRC (2002-2007)

Scientific Advisory Committee, 4th International Symposium on Microdialysis in Drug Research and Development, Vienna, Austria, June 2004

Scientific Advisory Committee, Abbott Laboratories, for the FDA Critical Path Initiative, September 2004 Scientific Advisory Committee, 5th International Symposium on Microdialysis in Drug Research and Development, Leiden, The Netherlands, June 2006

GLP-1 Scientific Advisory Panel, Medtronic, Minneapolis, MN, April 2009-present

MEMBERSHIP IN PROFESSIONAL AND SCIENTIFIC SOCIETIES

American Association of Pharmaceutical Scientists (Fellow)

American Association for the Advancement of Sciences (Fellow)

American Pharmacists Association (APhA)

American Society for Pharmacology and Experimental Therapeutics

International Society of Anti-Infective Pharmacology

International Society for the Study of Xenobiotics

Technology Park, Heidelberg, Germany

Century Mortar Club (Board of Directors, 1996-98)

Rho Chi Honor Society

SCHOLARSHIPS, HONORS AND AWARDS

1964	Scholarship, Canadian Foundation for the Advancement of Pharmacy
1965-66	National Research Council of Canada
1965	Warner-Lambert Research Fellowship
1968-70	National Institute of Health (NIH) Training Grant
1981-82	Teacher of the Year, College of Pharmacy, University of Minnesota
1986	Recipient of Horace T. Morse-Amoco Foundation Award
1988	Fellow, American Association of Pharmaceutical Scientists
1990	Fellow, American Association for the Advancement of Science
1996	Hallie Bruce Memorial Lecture Award
1997	Fellowship, Japanese Society for the Promotion of Science
1999	Meritorious Manuscript Award, American Association of Pharmaceutical Scientists
2001	Weaver Medal of Honor
2004	Distinguished Lecture, Creighton University School of Pharmacy and Health Professions
2005	Academy of Distinguished Teachers, University of Minnesota
2006	Distinguished Lecture, Temple University School of Pharmacy
2007	APhA Research Achievement Award in the Basic Pharmaceutical Sciences

COMMITTEE APPOINTMENTS

COLLEGE OF PHARMACY

1972-73, 1973-74	Student American Pharmaceutical Association Minnesota Chapter (Faculty Advisor)
1972-75	Student Admissions and Academic Standing Committee, College of Pharmacy
1972-73	Task Force on College of Pharmacy Organization
1973-74	Continuing Education Committee
1972-78	Admissions Committee for Pharm.D. Program, College of Pharmacy (Chair 1973-74; 1977-78)
1974-75	University of Minnesota Health Sciences B/C Implementation Committee
1974-77	Constitution and By-laws Committee
1974-75	Unit K Committee, Graduate School

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107F 76	Task Farra on Dharma D. Admissions
1975-76	Task Force on Pharm.D. Admissions
1976-78	Professional Education Committee
1977-78	Task Force on Travel
1977-78	Anatomy, Physiology, Pathology Study Group
1977-78	Drug Product Design and Evaluation Study Group
1976-78	Search Committee for Biopharmaceutics Faculty Member
1977-78	Search Committee for Assistant Director HCMC
1977-78	Search Committee for Research Associate, CEP Project D-1 (Chairman)
1978-79	Pharm.D. Program Planning Committee (Chairman)
1978-79, 1979-80	Computer Systems Committee (Chairman)
1979-80	Professional Education Committee (Chairman)
1980-81	Educational Policy Committee (Chairman)
1980-82	Externship Committee
1981-82	Academic Standing Committee
1981-83	Health Sciences Policy and Review Council
1981-82	Graduate Faculty Nominations and Course Proposals Committee
1982-83	Academic Standing Committee (Chairman)
1982-83	Advisory Committee on Animal Care Facilities
1983-85	Council of Directors of Graduate Studies
1982-83	Task Force on Computers
1983	Search Committee for Department Chairman (Chairman)
1983	Search Committee for Clinical Faculty at HCMC
1984	Ad Hoc Committee on External Pharm.D. Program
1984	Executive Committee (Chairman)
1984	Search Committee for Dean of College of Pharmacy
1984	Search Committee for Psychiatry Position, St. Paul-Ramsey Medical Center
1984	Search Committee for Clinical Faculty at Hennepin County Medical Center
1985	Endowed Chair in Pharmaceutics Search Committee (Chair)
1985	Assistant Professor in Pharmaceutics Search Committee (Chair)
1985	Appointment, Promotion and Tenure Committee
1985	Space Committee
1985	Clinical Assistant Professor (MMC) Search Committee
1985-89	Executive Committee
1986-87	Appointment, Promotion and Tenure Committee (Chair)
1986-90	Educational Policy Committee
1986-87	Subcommittee of Educational Policy Committee
1986	Search Committee for Endowed Chair (Chair)
1986-87	College of Pharmacy Strategic Planning Committee
1986-87	Subcommittee of Strategic Planning Committee to Develop College Goals and Objectives
1987-90	Continuing Pharmacy Education Advisory Committee (Chair)
1987-88	Admissions Committee
1988-89	Admissions Committee (Chair)
1989-91	Promotion and Tenure Committee
1991-92	Promotion and Tenure Committee (Chair-Elect)
1991-92	General Research Support Committee
1992-93	Promotion and Tenure Committee (Chair)
1992-93	General Research Support Committee
1993-94	Academic Standing Committee (Chair-Elect)
1994-95	Academic Standing Committee (Chair)
1994-98	College Computer Committee
1995-96	Promotion and Tenure Committee
1995-96	Internal Organization and Leadership Task Force
1996-97	Nontraditional Pharm.D. Task Force
1997-98	Search Committee for Endowed Chair in Geriatric Pharmacotherapy
	committee for Endowed Chair in Certaine Finding Control of the

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1997-98	Admissions Committee
1997-98	Search Committee for Immunotherapy Faculty Position (Chair)
1998-2000	Search Committee for Pharmaceutics Faculty Position
2000-2001	Educational Policy Committee
2001-2002	Search Committee for ECP Faculty Position
2001-2002	Educational Policy Committee (Chair)
2001-2002	Search Committee for Pharmaceutics Faculty Position
2001-2002	College of Pharmacy Phar. Sci. 2020 Committee, Capital Campaign (Co-Chair)
2001-2004	College of Pharmacy Faculty Consultative Committee
2002-2003	Educational Policy Committee (Past Chair)
2002-2003	College of Pharmacy Collegiate Review Committee (Chair)
2002-2003	College of Pharmacy Central Council (Faculty Representative)
2002-2003	College of Pharmacy Instructional Development Working Group for the Duluth Expansion
2003-2005	Search Committee for Pharmaceutics Faculty Position at UMD (Chair)
2004-2007	College of Pharmacy Assessment Committee
2005-2006	Search Committee for Endowed Chair in Geriatric Pharmacotherapy
2006-2007	Search Committee for Pharmaceutics Faculty Position

UNIVERSITY COMMITTEE APPOINTMENTS

1974-78

Forum
Health Sciences Primary Health Care Program Committee (Alternate),
Solicitor for the University of Minnesota Consolidated Fund Drive
Alternate Senator (U. of Minnesota)
Senator (U. of Minnesota)
Health Sciences Learning Resources Committee
College Delegate to All-University Single Quarter Leave Working Group, Academic Affairs
Health Sciences Policy and Review Council, Graduate School
Biological Sciences (formerly Plant and Animal Sciences) Policy and Review Council, Graduate
School
Graduate Faculty Nominations Subcommittee, Biological Sciences Policy and Review Council,
Graduate School
Graduate Faculty Nominations Subcommittee (Chair), Biological Sciences Policy and Review
Council, Graduate School
Biological Sciences Policy and Review Council, Graduate School
Faculty Research Development Proposal Review Committee for the Academic Health Center
Academic Health Center Faculty Consultative Committee
SCFP Subcommittee on Twin Cities Facilities and Support Services (STCFSS)
AHC Seed Grant Review Committee
AHC FCC Internal Screening Committee for Academy of Excellence Nominees
All-University Honors Committee, University of Minnesota

Subcommittee on Academic-Industrial Interface, Academic Relations Committee, 3M Technical

STATE, NATIONAL, AND INTERNATIONAL COMMITTEE APPOINTMENTS

1974-76	Representative to AACP Council of Faculties
1977-78	AACP Task Force on Guidelines for Pharm.D. Accreditation
1980-82	Academic Advisory Committee, Kellogg Pharmaceutical Scientist Program
1981	Screening Committee for Academy of Pharmaceutical Sciences, Basic Pharmaceutics Section
1989-present	Member, Scientific Committee, International Pharmaceutical Technology Symposium (FIP)
1990	Academic Affairs Committee, AACP (Member)
1990	Program Committee, Controlled Release Society Annual Meeting (Member)

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1989-91	Continuing Education Committee, State Board of Pharmacy (Member)
1990-95	USP Committee of Revision (Member)
1991-93	NIH/NINDS Antiepileptic Drug Development Program (Consultant)
1995	Fellows Nominations Committee for AAPS, PPDM Section
1995	Screening Committee for AAPS PPDM Section Abstracts
1997-2000	Fellows Nominations Committee for AAPS, PPDM Section
1999-2000	Committee on AAPS Section Structure and Procedure Guideline
2000-2001	PPDM Vice Chair, American Association of Pharmaceutical Scientists
2000-2002	Co-Chair, Organizing Committee, 3rd International Symposium on Microdialysis in Drug
	Research and Development
2001-2002	PPDM Chair Elect, American Association of Pharmaceutical Scientists
2001-2002	Annual Program Planning Committee, American Association of Pharmaceutical Scientists
2001-2002	Program Coordinating Committee, American Association of Pharmaceutical Scientists
2002-2003	PPDM Section Chair, American Association of Pharmaceutical Scientists
2002-2003	PPDM Committee for Graduate Student Symposium Awardees, American Association of
	Pharmaceutical Scientists
2002-2003	Short Course Program Review Team, American Association of Pharmaceutical Scientists
2003-2004	PPDM Section Past-Chair, American Association of Pharmaceutical Scientists
2004-2007	Member-at-Large, American Association of Pharmaceutical Scientists Executive Council
2004-2006	Clinical and Operational Working Group (CORWG), NASA
2004-2005	AAPS Executive Council Liaison to the Clinical Sciences section of AAPS
2005-2006	AAPS Executive Council Liaison to the DDD section of AAPS
2005-2006	AAPS Executive Council Liaison to the PDD section of AAPS
2005-2006	AAPS Executive Council Liaison to the 2006 Annual Meeting Program Committee
2005-2006	AAPS Executive Council Liaison to the 2006 Annual Meeting Screeners
2005-2006	AAPS Executive Council Liaison to the 2006 Program Coordination Committee
2006	AAPS Reference Resources Task Force
2006-2007	AAPS Executive Council Liaison to the APQ section of AAPS
2006-2007	AAPS Executive Council Liaison to the PT section of AAPS
2006-2007	AAPS Executive Council Liaison to the International Affairs Committee
2009-present	Epilepsy NINDS Steering Committee
2009-present	NINDS Consortium to Study Bioequivalence of AED Products

INVITED PRESENTATIONS

Continuing Education Program (6 hours) Minneapolis, MN, 1973.

Upper Midwest Hospital Conference, 1974.

Continuing Education Program (6 hours) Rochester, MN, 1974.

University of Illinois, Chicago, IL, 1974.

Department of Clinical Pharmacology, University of Minnesota, 1974.

AACP Annual Meeting and Teachers' Seminar (Workshop Leader), Lake Kiamesha, NY, 1975.

Debate Symposium, "Drug Product Selection," St. Paul, MN, 1977.

Continuing Education for Minneapolis Veteran Pharmacists (2 hours), Minneapolis, MN, 1978.

Continuing Education in Pharmacy (2 hours), Mankato, MN, 1978

Continuing Education in Pharmacy "Seminar at Sea" (4 hours of instruction), 1978.

HPLC Workshop, Invited Lecturer, Bloomington, MN, 1978.

University of Kentucky, Lexington, KY, 1979.

American Association of Clinical Chemists, Midwest Section, Minneapolis, MN, 1979.

University of Illinois, Chicago, IL, 1979.

Smith Kline Corp., Philadelphia, PA, 1979.

Department of Pathology, St. Cloud Hospital, St. Cloud, MN, 1979.

Comprehensive Epilepsy Program, Minneapolis, MN, 1979.

University of North Carolina, Chapel Hill, NC, 1979.

Burroughs Wellcome Co., Research Triangle Park, NC, 1979.

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St. Paul-Ramsey Medical Center, St. Paul, MN, 1989.

Continuing Education in Pharmacy (4 hours) Minneapolis, MN, September-October, 1981.

Medical Research Council of Canada, Visiting Professor, University of British Columbia, Vancouver, 1982.

Invited Lecturer, National Institutes of Health, Epilepsy Branch, Bethesda, MD, 1982.

Geriatric Research, Education and Clinical Center, Bloomington, MN, September, 1982.

Continuing Education in Pharmacy (6 hours), Duluth, MN, September, 1982.

Ciba-Geigy, Pharmaceuticals Division, Ardsley, December 2, 1982.

Swiss Federal Institute of Technology, Zurich, Switzerland, June 19, 1984.

Biopharmacy Division, Sandoz AG, Basel, Switzerland, June 22, 1984.

Biopharmacy Division, Sandoz AG, Basel, Switzerland, July 24, 1984.

"Cyclosporine Pharmacokinetics in the Rabbit: <u>In Vivo</u> Disposition and <u>In Situ</u> Absorption Studies," Rhone-Poulenc Visiting Professor, University of Toronto, Ontario, February 5, 1985.

"Pharmacokinetics and Pharmacodynamics," Drug Therapy Symposium VI, St. Paul, MN, February 27, 1985.

"Absorption and Disposition Studies with Cyclosporine," Sandoz, AG, Basel, Switzerland, July 15, 1985.

"Absorption of Cyclosporine from Rabbit Small Intestine Using an In Situ Perfusion Model," Vorstand des Instituts fur Pharmazie U. Lebensmittlechemie der Ludwig-Maximilians-Universitat, Munich, West Germany, July 17, 1985.

"Analytic considerations in the Investigation of the Pharmacokinetics of Cyclosporine," Medizinischen Hochschule, Hanover, West Germany, September 11, 1985.

"Mixed-Order Absorption of a Sustained Release Carbamazepine Tablet in Humans," Institut fur Pharmazeutische Technologie der Johann Wolfgang Goethe-Universitat, Frankfurt am Main, West Germany, May 15, 1986.

"Simultaneous First- and Zero-order Absorption of Commercial Carbamazepine Tablets," 5th Symposium on Biopharmaceutics and Pharmacokinetics, Piestany, Czechoslovakia, May 22, 1986.

"Simultaneous First- and Zero-order Absorption of Tegretol in Human Volunteers," National Institutes of Health, Epilepsy Branch, NINCDS, Bethesda, MD, November 6, 1986.

"Comparison of Plasma AUCs using the Traditional Point-by-Point and Pooled Sample Methods: Application in the Analysis of Human Pharmacokinetics of Carbamazepine and its metabolites," Food and Drug Administration, Rockville, MD, July 20, 1987.

"Pharmacokinetics in Contemporary Pharmacy Practice," Minneapolis Veteran Pharmacists Association, Richfield, MN, September 15, 1987.

"The Absorption and Disposition Kinetics of Carbamazepine and its Metabolites in Humans," Ciba-Geigy, Summit, NJ, July 23, 1987.

The following four lectures were given in Beijing, Chengdu, and Guilin, China during a visit sponsored by the Chinese Academy of Medical Sciences in late October/early November 1987:

- 1. "Theory and Application of a Pharmacokinetic Model in Individualizing Dosing Regimens for the Aminoglycosides."
- 2. "First- and Zero-order Absorption of Carbamazepine from Commercial Tablets in Epileptic Patients and Normal Volunteers."
- 3. "Significance of Nonlinear Disposition Kinetics in the Adjustment of Dosing Regimens."
- 4. "Relative Bioavailability of Phenytoin Formulations: Problems in Assessment Due to Michaelis-Menten Elimination Kinetics."

"Does Tegretol need to be Dosed TID?" Comprehensive Epilepsy Program, Minneapolis, MN, March 21, 1988.

"The Kinetics of Absorption of Carbamazepine (Tegretol) and its Metabolism in Humans," Vorstand des Instituts der Pharmazie, Ludwig-Maximilians Universitat, Munich FRG, June 8, 1988.

"Pharmacokinetic and Physiologic Considerations in Oral Controlled Drug Delivery," Novel Drug Delivery Symposium, Minneapolis, MN, September 20, 1988.

"Clinical Applications of the Two-Compartment Open Model," Regional Kidney Disease Program, Hennepin County Medical Center, Minneapolis, MN, November 16, 1988.

The following five lectures were presented in a Continuing Education in Pharmacy Program: "Concepts and Applications in Pharmacokinetics, Parts I and II"; "Therapeutic Response and Toxicity"; "Monitoring Drug Therapy"; and "Bioavailability and Bioequivalence", St. Thomas, Virgin Islands, March 8-13, 1989.

"The Pharmacokinetics of Zidovudine (AZT) with Some Observations on the Interaction with Probenecid," Queen's University of Belfast, Belfast, North Ireland, June 15, 1989.

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- "Pharmacokinetic and Analytical Considerations in Monitoring Zidovudine (AZT) Levels in Children with Aids," Fourth International Congress on Pediatric Laboratory Medicine, Washington, DC, August 23, 1989.
- "Inhibition of Zidovudine Metabolism and Excretory Transport," Department of Pharmacodynamics, Semmelweis University of Medicine, Budapest, Hungary, September 13, 1989.
- "Evaluating Bioequivalence," Western Michigan Society of Hospital Pharmacists, Grand Rapids, MI, March 2, 1990.
- "Effect of Temperature and Medium of Analysis on Cyclosporine Concentration," Canadian Consensus Meeting on Cyclosporine Monitoring, Minaki Lodge, Canada, May 11, 1990.
- "Studies of the Interaction between Zidovudine (AZT) and Probenecid in Animals and Humans." Pharmaceutics and Process R & D, Ayerst Laboratories Inc., Rouse's Point, NY, August 17, 1990.
- "Mechanistic Studies to Examine the Effect of Probenecid on the Brain Uptake of Zidovudine," Shanghai Medical University, Shanghai, P.R.C., October 13, 1990.
- A lecture series (16 hrs) on the topic of "Clinical Pharmacokinetics and Therapeutic Drug Monitoring" was given to staff members of the Chinese Academy of Medical Sciences and Hospital Pharmacists, Beijing, P.R.C., October 15-20, 1990.
- "Comparative Intestinal Absorption of Compounds of Varying Lipophilicity, and the Effect of Absorptive Water Flux." Lederle Laboratories, Pearl River, NY, September 12, 1991.
- "Analysis of Zidovudine Distribution into Specific Brain Regions Utilizing Microdialysis," Bristol Myers-Squibb Research Institute, Princeton, NJ, September 17, 1991.
- "Distribution of AZT Into Specific Brain Regions in the Rabbit Utilizing Microdialysis," University of Illinois College of Medicine, Peoria, IL, October 9, 1991.
- "Studies on the Transport of Nucleosides into Specific Brain Regions Using Microdialysis with *In Vivo* Calibration." University of Florida, College of Pharmacy, Gainesville, FL, December 6, 1991.
- "Analysis of Zidovudine Distribution into Specific Brain Regions Utilizing Microdialysis," University of Arizona College of Pharmacy, Tucson, AZ, February 17, 1992.
- "Regional Considerations in the In Situ Intestinal Absorption of Glycylcycline and Minocycline, and the Effect of Solvent Drag," Lederle Laboratories, Pearl River, NY, May 11, 1992.
- "Comparative Absorption of Fluorothymidine and Related Nucleosides in Different Anatomic Intestinal Regions," Lederle Laboratories, Pearl River, NY, May 11, 1992.
- "Microdialysis Techniques for the Study of Drug Distribution, and the Problem of Recovery *In Vivo*," Europhor Toulouse, France, June 19, 1992.
- "The Use of Microdialysis in Studying the Distribution of Exogenous Substances in Biological Tissues," Sandoz Pharma, Basel Switzerland, June 24, 1992.
- "Inhibition of Brain Distribution and Systemic Clearance of AZT by Probenecid," Sandoz Pharma, Basel Switzerland, June 30, 1992.
- "Uptake of Zidovudine (AZT) into Rabbit Brain Using Microdialysis with *In Vivo* Calibration," Knoll AG, Ludwigshafen, Germany, July 1, 1992.
- "Microdialysis in the Study of the Distribution and Metabolism of Exogenous Substances," Pharmaceutical Chemical Institute, University of Heidelberg, Heidelberg, Germany, July 2, 1992.
- "The Relationship Between Urine and Plasma Concentrations of Lipophilic Drugs: Implications for Therapeutic Drug Monitoring," Sandoz Pharma, Basel Switzerland, July 8, 1992.
- "Estimation of the Elimination Rate Constant for Metabolites which Exhibit Formation-Rate Limited Disappearance," Sandoz Pharma, Basel Switzerland, July 23, 1992.
- "Experimental Determination of Free Tissue Levels Using Microdialysis," 4th Biennial Conference on Chemotherapy of Infectious Diseases and Malignancies, Prague, Czechoslovakia, August 31, 1992.
- "In Situ Intestinal Absorption of Tetracycline Derivatives and the Effect of Absorptive Water Flux," Lederle Laboratories, Pearl River, NY, November 13, 1992.
- "Reversibility of Carbamazepine Autoinduction upon Dose Termination in Normal Volunteers," Abbott Laboratories, Abbott Park, IL, December 2, 1992.
- "Barriers to the Oral Delivery of Drugs," Wyeth-Ayerst Research, Radnor, PA, February 23, 1993.
- "Preliminary Results of Studies which Examine the Distribution of the NMDA Antagonist, EAB 515, to Rat Brain," Sandoz Pharma, Basel Switzerland, April 26, 1993.
- "Microdialysis Calibration Using the Zero-Net Flux Method and Retrodialysis in Studying the Distribution of Exogenous Substances to Rat Brain," Sandoz Pharma, Basel Switzerland, April 26, 1993.

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- "Investigation of the Pharmacodynamics of the NMDA Antagonist, EAB 515, in the Rat During Intravenous and Intracerebroventricular Administration." Sandoz Research Institute, Berne, Switzerland, April 28, 1993.
- "Comparative Distribution of AZT to Brain Tissue Extracellular Fluid During Intravenous and Intracerebroventricular Infusion." Food and Drug Administration, Rockville, MD, May 21, 1993.
- "Interspecies Scaling of Pharmacokinetics in the Evaluation and Development of New Antiepileptic Drugs." Natural Resources Research Institute, University of Minnesota Duluth, Duluth, MN, August 11, 1993.
- "Application of Pharmacokinetic Principles in Practice." Minneapolis Veteran Pharmacists Association, St. Louis Park, MN, September 21, 1993.
- "Microdialysis as a Tool to Study Drug Delivery to the Brain." North Jersey American Chemical Society Drug Metabolism Discussion Group, Somerset, NJ, October 7, 1993.
- "Graduate Studies and Research Careers in Pharmaceutics." University of Minnesota—Duluth Department of Chemistry, Duluth, MN, December 3, 1993.
- "Microdialysis in Pharmacokinetic and Drug Metabolism Studies." 95th Annual Meeting, American Society for Clinical Pharmacology and Therapeutics, New Orleans, LA, April 1, 1994.
- "Modeling and Simulation of Complex Pharmacokinetic Systems." NATO Advanced Study Institute, Erice, Italy, April 12, 1994.
- "Microdialysis in the Study of Drug Distribution." NATO Advanced Study Institute, Erice, Italy, April 13, 1994.
- "Pharmacokinetic Studies Utilizing Microdialysis." Department of Pharmaceutical Chemistry, University of Kansas, Lawrence, KS, May 2, 1994.
- "Pharmacokinetic Studies Utilizing Microdialysis and On-Line HPLC." 4th International Workshop in Bioanalysis, Lawrence, KS, July 12, 1994.
- "Application of Microdialysis in Pharmacokinetic Studies." Gordon Research Conference in Drug Metabolism, Holderness School, Plymouth, NH, July 20, 1994.
- "Microdialysis and its Application in Pharmacokinetic Studies." Ciba-Geigy, Pharmacokinetics and Bioanalytics Division, Ardsley, NY, July 25, 1994.
- "Assessing Drug Transport in the Brain with Microdialysis." 9th Annual Meeting, American Association of Pharmaceutical Scientists, San Diego, CA, November 6-10, 1994.
- "Applications of Microdialysis in Preclinical Pharmacokinetic Studies." 3M Pharmaceuticals, 3M Center, St. Paul, MN, November 29, 1994.
- "Problems in Assessing the Absorption of Carbamazepine from Sustained Release Dosage Forms in Epileptic Patients." Pharmavene, Inc., Gaithersburg, MD, February 23, 1995.
- "Selected Preclinical Pharmacokinetic Studies with Tacrine." Parke-Davis Pharmaceuticals, Ann Arbor, MI, May 5, 1995.
- "Brain Distribution and Metabolism Studies with Tacrine and Two Hydroxylated Metabolites." Department of Pharmaceutics and Pharmacodynamics, University of Illinois, Chicago, IL, July 28, 1995.
- "Microdialysis and its Application in Preclinical Drug Distribution and Absorption Studies." Chiron Corporation, Emeryville, CA, August 18, 1995.
- "The Principle of Quantitative Microdialysis and its Application in Preclinical Drug Distribution Studies." Genentech, Inc., South San Francisco, CA, October 9, 1995.
- "Graduate Programs and Research Opportunities in Pharmaceutics." 13th Annual Symposium on Pharmaceutical Sciences Graduate Programs, Merrillville, IN, October 21, 1995.
- "Principles of Microdialysis and Applications in Preclinical Drug Distribution and Absorption Studies," Wyeth-Ayerst, Pearl River, NY, December 6, 1995.
- "Microdialysis in Preclinical Drug Distribution Studies." Dupont Merck, Newark, DE, December 8, 1995.
- "Microdialysis and its Application to the Study of Drug/Metabolite Distribution in the Central Nervous System," University of Pittsburgh, PA, January 25, 1996.
- "Therapeutic Drug Monitoring: A Fodor's Guide." Hallie Bruce Memorial Lecture Award, Minnesota Society of Health-Services Pharmacists, Minneapolis, MN, April 13, 1996"
- "Preclinical Studies of Drug Distribution to the Brain using Microdialysis." Pharmaceutical Peptides Inc, Cambridge, MA, May 2, 1996.
- "Microdialysis and its Application in Nonclinical Studies of Drug Distribution and Absorption." Bristol-Myers Squibb, Pinceton, NJ, June 24, 1996.
- "Continuous Monitoring by Microdialysis in Neuropharmacokinetic Investigations." Faculty of Pharmacy, University of Tanta, Tanta, Egypt, March 5, 1997.

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- "Preclinical Studies of Drug Distribution to the Brain using Microdialysis," Toyama Medical and Pharmaceutical University, Toyama, Japan, April 11, 1997.
- "Application of Pharmacokinetic Principles in Individualizing Aminoglycoside Dosing," Toyama Medical and Pharmaceutical University, Toyama, Japan, April 11, 1997.
- "Preclinical Studies of Drug Distribution to the Brain using Microdialysis," Meiji College of Pharmacy, Japan, April 18, 1997.
- "Individualizing Aminoglycoside Dosing and Once-a-Day Aminoglyocosides," Meiji College of Pharmacy, Japan, April 18, 1997.
- "Education of Pharmacists and Pharmaceutical Scientists at the University of Minnesota," 260th Meeting on Continuing Education of Pharmacists, Okuda-Shinmachi, Toyama, Japan, April 26, 1997.
- "Pharmacokinetic Basis of Drug-drug Interactions," Novartis Workshop on Metabolic Drug-Drug Interactions, Schluchsee, Germany, October 14, 1997.
- "Microdialysis and its Application in Preclinical Pharmacokinetic Studies," Merck Research Laboratories, West Point PA, December 16, 1997.
- "Microdialysis and its Application in Preclinical Pharmacokinetic Studies," Merck and Co, Inc. Rahway NJ, December 17, 1997.
- "Brain Distribution Studies employing Microdialysis and Crossover Designs," 1st International Symposium in Drug Research and Development, Noorwijkerhout, Netherlands, April 3, 1998.
- "Application of Sample Pooling in the Time Domain to Estimate CL, Vss and MRT in the Search for Lead Compounds." Chiron Corporation, Emeryville, CA, May 5, 1998.
- "Microdialysis as a Sampling Technique in Preclinical Pharmacokinetic Studies." Pfizer Inc, Groton CT, June 18,1998
- "Assessing Drug Delivery to the CNS Using Microdialysis Sampling." School of Medicine, University of Minnesota, Duluth, October 19,1998.
- "Pharmacokinetic Studies Using Microdialysis Sampling." American Association of Pharmaceutical Scientists Annual Meeting, San Francisco CA, November 18, 1998.
- "Applications of Microdialysis in Pharmacokinetics: Brain, Blood, and Middle Ear Fluid." Bristol-Myers Squibb, Wallingford CT, May 14, 1999.
- "Applications of Microdialysis in Preclinical Pharmacokinetics: Brain, Blood and Middle Ear Fluid." Parke-Davis, Ann Arbor, MI, May 21, 1999.
- "Blood Sample Pooling and the Determination of Mean Residence Times in High-Throughput Pharmacokinetic Screening"." Parke-Davis, Ann Arbor, MI, May 21, 1999.
- "Role of controlled release formulations in the steady-state pharmacokinetics and pharmacodynamics of anticonvulsants" Impax Pharmaceuticals, Inc, Hayward CA, June 9, 1999.
- "Investigating Neuropharmacokinetics and Drug Delivery to the CNS using Microdialysis." 8th International Conference on In Vivo Methods: Monitoring Molecules in Neuroscience. Stony Brook NY, June 19-23, 1999.
- "Use of Microdialysis in Pharmacokinetics" at the 8th BMSR Workshop on Advanced Methods of Pharmacokinetic and Pharmacodynamic System Analysis, Marina del Rey, CA June 25-26, 1999.
- "Applications of Microdialysis in Preclinical Pharmacokinetics." Amgen, Inc., Thousand Oaks, CA, June 28, 1999.
- "Pharmacokinetic -Pharmacodynamic Principles in Drug Development." Chiron Corporation, Emeryville, CA, August 20, 1999.
- "Microdialysis and its Application in Pharmacokinetics: Brain, Blood, and Middle Ear Fluid." Abbott Labs, Abbott Park IL Aug 27, 1999.
- "Distribution kinetics of antibiotics to the chinchilla middle ear" Department of Biopharmaceutical Sciences, Uppsala University, Uppsala, Sweden, March 16, 2000
- "In Vivo Microdialysis as a Tool to Study Site Specific Drug Delivery" *Millennial World Congress of Pharmaceutical Sciences*. San Francisco CA, April 17, 2000
- "In Vivo Microdialysis as a Tool to Study Site Specific Drug Delivery" *Engebretson Symposium on Drug Discovery and Development*. Minneapolis, MN. May 18, 2000
- "In Vivo Microdialysis as a Tool to Study Drug Delivery". 19th Annual Robert S. Rozman Memorial Symposium, Langhorne PA, May 25, 2000
- "Basic Principles of Microdialysis, Experimental Setup". Course on Basic and Advanced Aspects of In Vivo Microdialysis", Stockholm, Sweden, June14, 2000.

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- "Recovery: Basic Idea and Practical Methods". Course on Basic and Advanced Aspects of In Vivo Microdialysis", Stockholm, Sweden, June14, 2000.
- "Studies of Distribution of Antibiotics to the Middle Ear by Microdialysis" 2nd International Symposium on Microdialysis in Drug Research and Development, Stockholm, Sweden, June15, 2000.
- "Basic Concepts in Clinical Pharmacokinetics" A 2-Day Course. Abbott Laboratories, Abbott Park IL and Victory Hospital, Waukegan, IL, July 18-19, 2000
- "Microdialysis and its Application in Preclinical Pharmacokinetics: Brain, Blood, and Middle Ear Fluid." Dupont Pharmaceuticals, Wilmington, DE July12, 2000.
- "Pharmacokinetic Pharmacodynamic Principles in Drug Development." Abbott Labs, Abbott Park IL Jan 9, 2001
- "Biopharmaceutical and Pharmacokinetic Considerations in Delivering Drug to the CNS" Medtronic Neuro Division, Minneapolis. January 25, 2001
- "Clinical Pharmacokinetic Principles in Drug Development." Novartis Pharma, Tokyo, April 12, 2001
- "In Vivo Microdialysis as a Tool to Study Site Specific Drug Delivery" Showa University, Tokyo, Japan, April 13, 2001
- "In Vivo Microdialysis as a Tool to Study Drug Delivery in Preclinical Studies". Xi'an Medical College, Xi'an, PRC. April 25, 2001
- "Principles of Pharmacokinetics and their Application in Drug Development" Novartis Pharma, Basel, Switzerland, July 3, 2001.
- "Microdialysis and its Application in Preclinical Studies of Drug Delivery to Target Tissues" Boehringer-Ingelheim Pharma KG, Dept. of Pharmacokinetics & Drug Metabolism, Biberach, Germany, July 5, 2001.
- "Estimation of Intrinsic Clearances and Organ Partition Coefficients in an Organ Perfusion Model" Novartis Pharma, Basel, Switzerland, July 26, 2001.
- "Pharmacodynamic Modeling of the Sigmoid Emax Model" Novartis Pharma, Basel, Switzerland, July 31, 2001.
- "Prediction of the Pharmacokinetics of Cefdinir in Children from the Results of Animal Studies. Omnicef® Clinical Advisory Meeting, Dallas, TX, February 9, 2002.
- "Applications of Microdialysis in Studying Drug Delivery to Specific Targets". Guilin Medical School, Guilin PRC, March 28, 2002
- "Microdialysis: A Tool to Study Brain Uptake?" Gordon Research Conference on the Barriers of the CNS, Tilton School, Tilton NH, June 25, 2002
- "A Model for the Distribution of Drugs between Plasma, CSF and Parenchyma", Workshop on Microdialysis Techniques in the CNS, Gordon Research Conference on the Barriers of the CNS, Tilton School, Tilton NH, June 26, 2002
- "Microdialysis in the Study of Drug Delivery to the Central Nervous System", Department of Pharmaceutics, Seoul National University, Seoul, South Korea, November 25, 2002.
- "Investigating Antibiotic Delivery to the Middle Ear". Chong Kun Dang Pharma, Cheonan, South Korea, November 27, 2002
- "Microdialysis and its Application in Preclinical Pharmacokinetic and Drug Delivery Investigations", 32nd Annual Meeting of the Korean Pharmaceutical Society, Seoul, South Korea, November 28, 2002.
- "Applications of Pharmacokinetic Principles in Drug Development". Schering-Plough Research Institute. Kenilworth, NJ. December 19, 2002
- "A Course in Pharmacokinetics in Pharmaceutical Development". Abbott Laboratories. Harrison Conference Center, Lake Bluff, IL. May 15-16, 2003
- "Characterizing Antibiotic Delivery to the Middle Ear for the Treatment of Otitis Media. Biomedical Simulations Resource Workshop: Advanced Methods of PK/PD Systems Analysis. Marina del Rey, CA. June 20-21, 2003.
- "Cerebrospinal Fluid Distribution of Intrathecally Administered Antiviral Nucleosides". Monitoring Molecules in Neuroscience. 10th International Conference on In Vivo Methods. Department of Neuroscience, Karolinska Institutet Stockholm, Sweden. June 24-27, 2003
- "Microdialysis Sampling in Drug Development: Applications in Preclinical Research." Sunrise School, American Association of Pharmaceutical Scientists Annual Meeting, Salt Lake City, UT, October 26, 2003.

- "Clinical Pharmacokinetics in Pharmaceutical Development." Abbott Laboratories. Harrison Conference Center, Lake Bluff, IL. July 23-24, 2003.
- "Microdialysis Sampling in Drug Development: Applications in Preclinical Research." Sunrise School, American Association of Pharmaceutical Scientists Annual Meeting, Salt Lake City, UT. October 26, 2003.
- "The Role of Pharmacokinetics in Drug Discovery." Abbott Laboratories. Harrison Conference Center, Lake Bluff, IL. March 18, 2004.
- "Microdialysis and its Application in Preclinical Pharmacokinetic and Drug Delivery Investigations." CDER, Food and Drug Administration, Rockville, MD. March 29, 2004.
- "Interspecies Scaling, PB-PK modeling and Microdialysis in Antibiotic Drug Development." Novartis Institute for Biomedical Research, Cambridge, MA. April 9, 2004.
- "Does it get to the Target Site? Microdialysis as a Tool to Study Preclinical Drug Distribution and Delivery" Amgen Inc., Thousand Oaks, CA. April 30, 2004.
- "Microdialysis of Antibiotics." 4th International Symposium on Microdialysis in Drug Research and Development, Vienna, Austria, June 19, 2004.
- "The Chinchilla Microdialysis AOM Model" Pfizer Global Pharmaceuticals, New York, NY. June 25, 2004.
- "Advantages of the Chinchilla Microdialysis Model" Scientific Basis for Tissue-Directed Antimicrobial Therapy Symposium, Boston MA, July 21-22, 2004.
- "Evaluating Drug Distribution to the Target Site and Predicting Tissue Exposure in Humans from Animal Data" Scientific Advisory Committee, Abbott Laboratories. The FDA Critical Path Initiative and the Role of Modeling/Simulation in Improving the Efficiency of Drug Development. Lake Forest, IL. September 8-9, 2004.
- "Assessing Drug Delivery to the Target Site: The Role of Microdialysis in Measuring Tissue Exposure in Animals and Humans." Distinguished Lecture, Creighton University School of Pharmacy and Health Professions, Omaha NE, November 30, 2004.
- "Microdialysis—Introduction to Basic Principles and Applications". AAPS Workshop on Microdialysis Principles, Application, and Regulatory Perspectives, Nashville TN, November 4, 2005.
- "A Phase I Open-Label, Dose-Ranging Study to Investigate the Safety and Tolerability of Gabapentin Injection Administered Intrathecally in Individuals with Chronic, Intractable Pain: A Pharmacokinetic Report". Medtronic WHQ, Fridley, MN, February 16, 2006.
- "Public Outreach and AAPS: Students are the Future of Our Association". Temple University School of Pharmacy, Philadelphia, PA. February 20, 2006.
- "Assessing Drug Delivery: Using Microdialysis to Measure Target Site Exposure in Animals and Humans". Wyeth Distinguished Lecture Series, Temple University School of Pharmacy, Philadelphia, PA. February 20, 2006.
- "Pharmacokinetics for Scientists Engaged in Drug Discovery". Lundbeck Research, USA. Paramus NJ. February 24, 2006.
- "Pharmacokinetic Issues related to Intrathecal Drug Dosing". Medtronic WHQ, Fridley, MN, March 15, 2006.
- "TTM Technology: Antibiotic Distribution to Middle Ear Fluid" Abbott Laboratories, Abbott Park, IL. May 16, 2006.
- "Trans-tympanic Membrane (TTM) Drug Delivery to the Middle Ear" Alcon Laboratories, Fort Worth TX. Feb 2, 2007.
- "Bugs and Drugs: Does the Anti-infective Agent get to the Target Site?". Science Luncheon Presentation. APhA Annual Meeting. Atlanta, GA. March 18, 2007
- "Future Perspectives on the Contributions of Microdialysis in Drug Research and Development" Keynote Address. Fifth International Symposium on Microdialysis in Drug Research and Development. Leiden, NE. April 25, 2007.
- "Drug Delivery to the Middle Ear across the Tympanic Membrane for Therapy of Acute Otitis Media". Global Gators 6th Symposium on Clinical Pharmacy and Clinical Pharmacology. Munich, Germany. June 9, 2007.
- "The Pharmacokinetics of Hydrophilic Drugs during Intrathecal Infusion: the Concept of a Targeted Delivery Advantage". Novartis Pharma AG, Basel, Switzerland. June 13, 2007.

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[&]quot;Trans-tympanic Membrane Delivery of Moxifloxacin into Chinchilla Middle Ear" Alcon Laboratories, Fort Worth TX. October 15, 2008.

[&]quot;A Phase I Study to Investigate the Safety and Pharmacokinetics of Intrathecal Gabapentin Injection in Individuals with Chronic Pain". University of Poitiers, Poitiers, France, April 29, 2009.

TEACHING AT THE UNIVERSITY OF MINNESOTA

<u>Undergraduate</u>

1971 - 1972	Co-instructor in Phar 5680 "Pharmacokinetics"
1971 - 1975	Discussant in Pharm.D. Conferences
1972 - 1973	Participating instructor in Phar 5670
1972 - 1978	Discussion leader in Pharm.D. I conferences
1972 - 1985	Course director, Phar 5680 "Pharmacokinetics"
1975 - 1995	Course director, Phar 5685 "Clinical Pharmacokinetics"
1991 - 1999	Course director, Phar 5681 "Basic Pharmacokinetic Modeling"
1996 - 1998	Course director and Participating instructor, Phmc 5460 "Pharmacokinetics"
1998 - 2003	Course director and instructor, Phar 6216 "Pharmacokinetic Simulation and Data Analysis
	using SAAM "
1999 - 2004	Course director and Participating instructor, Phar 6163 "Pharmacokinetics"
1998 - 2004	Participating instructor in Phar 6164 "Biopharmaceutics"
2004 - present	Participating instructor, Phar 6163 "Pharmacokinetics"
<u>Graduate</u>	
1972 - 1999	Course director in Phm 8420 "Modeling Approaches in Pharmacokinetics"
	participating instructor in Phm 8421, Phm 8425
1972 - 2005	Participating instructor in Phm 8100 (Seminar) and Phm 8101 (Pharmaceutics Readings)
1984 - 1999	Participating instructor in Phm 8425 "Advanced Topics in Pharmacokinetics"
1986 - 1999	Course co-director in Phm 8105 "Pharmacokinetics Research Seminar"
2000 - 2006	Course co-director in Phm 8150 "Pharmacokinetics Research Seminar"

TEACHING AT OTHER SITES

2000 - 2006

2004 - present 2006 - present Participating instructor in Phm 8481 "Advanced Neuropharmaceutics"

Participating instructor in Phm 8421 "Advanced Pharmacokinetics"

Course Co-director and Participating instructor in Phm 8421 "Advanced Pharmacokinetics"

[&]quot;An Introduction to Clinical Pharmacokinetics" Abbott Laboratories. Abbott Park, IL, January 9-10, 2001.

[&]quot;An Introduction to Clinical Pharmacokinetics" Abbott Laboratories. Abbott Park, IL, March 29-30, 2001.

[&]quot;An Introduction to Clinical Pharmacokinetics" Abbott Laboratories. Abbott Park, IL, May 17-18, 2001.

[&]quot;An Introduction to Clinical Pharmacokinetics" Abbott Laboratories. Abbott Park, IL, May 17-18, 2001.

[&]quot;An Introduction to Clinical Pharmacokinetics" Abbott Laboratories. Lake Bluff, IL, November 8-9, 2001.

[&]quot;An Introduction to Pharmacokinetics" Abbott Laboratories. Lake Bluff, IL, March 14-15, 2002.

[&]quot;An Introduction to Pharmacokinetics" Abbott Laboratories. Abbott Park, IL, July 22-23, 2002.

[&]quot;An Introduction to Pharmacokinetics" Abbott Laboratories. Parsippany, NJ, Aug 26-27, 2002.

[&]quot;An Introduction to Pharmacokinetics" Bristol-Myers Squibb. Wilmington, DE, September 19-20, 2002.

[&]quot;An Introduction to Pharmacokinetics" Schering Plough Corp. Kenilworth, NJ, December 19-20, 2002.

[&]quot;An Introduction to Pharmacokinetics" Abbott Laboratories. Lake Bluff, IL, July 23-24, 2003.

[&]quot;Short Course in Pharmacokinetics for Drug Discovery" Abbott Laboratories. Lake Bluff, IL. March 17, 2004.

[&]quot;Preclinical Pharmacokinetics in Pharmaceutical Discovery." Bristol-Myers Squibb, Princeton, NJ. May 6-7, 2004.

[&]quot;Introduction to Pharmacokinetics" Abbott Laboratories. Abbott Park, IL, July 27-28, 2004.

[&]quot;Introduction to Clinical Pharmacokinetics" Millennium Pharmaceuticals, Inc. Cambridge, MA, December 2-3, 2004.

[&]quot;Introduction to Clinical Pharmacokinetics" Gilead Sciences, Foster City, CA, December 8-9, 2005.

[&]quot;Basic Pharmacokinetic Concepts for the Pharmaceutical Scientist" Co-instructor. Boehringer-Ingelheim

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Pharmaceuticals, Inc, USA. Ridgefield, CT, April 13-14, 2006

"An Introduction to Pharmacokinetics" Lundbeck Research, USA, Inc. Paramus, NJ, February 24, 2006.

"Basic Pharmacokinetic Concepts for the Pharmaceutical Scientist" Co-instructor. Abbott Laboratories. Abbott Park, IL, June 4-5, 2007.

"Basic Pharmacokinetic Concepts for the Pharmaceutical Scientist" Co-instructor. Theravance, Inc. South San Francisco, CA, August 20-21, 2007.

"Basic Pharmacokinetic Concepts" Co-instructor. US Patent and Trademark Office. Alexandria, VA, October 4, 2007.

"Basic Pharmacokinetic Concepts for the Pharmaceutical Scientist" Co-instructor. Allergan, Inc. Irvine, CA. July 24-25, 2008.

"Basic Pharmacokinetic Concepts for the Pharmaceutical Scientist" Co-instructor. Abbott Laboratories, Abbott Park, IL. August 19-20, 2008.

"Basic Pharmacokinetic Concepts for the Pharmaceutical Scientist" Co-instructor. Gilead Sciences, Foster City, CA, October 9-10, 2008.

"Basic Pharmacokinetic Concepts for the Pharmaceutical Scientist" Co-instructor. Genentech, South San Francisco, CA, July 23-24, 2009.

"Basic Pharmacokinetic Concepts for the Pharmaceutical Scientist" Co-instructor. Abbott Laboratories. Abbott Park, IL, July 30-31, 2009.

TEACHING (CONT'D)

Graduate Students Advised:

1978	Wargin, W.A.	Ph.D.
1978	El-Yazigi, A.	Ph.D.
1980	Mugure Pyron	M.S.
1981	Sue-Chi Wu	M.S.
1983	Hsuehling Su	M.S.
1984	Dale Yu	Ph.D.
1984	Walid Awni	Ph.D.
1985	Lillian Riad	M.S.
1985	Rose Eggerth	Ph.D.
1987	Hisham Abou-Auda	Ph.D.
1989	Mohsen Hedaya	Ph.D.
1989	Ajit K. Shah	Ph.D.
1989	Lillian Riad	Ph.D.
1991	Helen Chan	Ph.D.
1992	William Elmquist	Ph.D.
1992	Shekman Wong	Ph.D.
1994	Yanfeng Wang	Ph.D.
1994	Bimal Malhotra	Ph.D.
1996	Richard Brundage	Ph.D.
1997	Zheng Yang	Ph.D
1998	Belinda Cheung	Ph.D.
2001	Yue Huang	Ph.D
2001	Guanfa Gan	Ph.D.
2002	Joanna Peng	Ph.D
2002	Tong Zhu	Ph.D.
2004	Ji Ping	Ph.D
2004	Wei Liu	Ph.D.
2005	Yan Song	Ph.D.
2007	Nael Mostafa	Ph.D.
2007	Zhihong Li	Ph.D.

GRANTS, CONTRACTS, and OTHER SUPPORT

1972-73	University of Minnesota Graduate School
1973-74	University of Minnesota Media Production Fund
1975-78; 1978-80	NIH/NINCDS Comprehensive Epilepsy Program Contract (Principal Investigator, Project D-1)
1976; 1977	Medical Education and Research Foundation Grant (Co-investigator with
1976-78	John W. McBride, M.D.) FDA Contract to Study the Pharmacokinetics and Toxicology of Phenytoin Sodium Products
1980-81; 1981-83	in Clinical Patients Grant to Support Research Involving the Analysis of Cyclosporin A in Biological Fluids
1982-83; 1983-84	(Sandoz, Inc.) "Pharmacokinetics and Biopharmaceutic Studies of Cyclosporin A in Selected Animal and <i>In Vitro</i> Systems" (NIH; Principal Investigator; Co-investigator, R.P. Enever)
1984	Comparative Bioavailability of Sodium Phenytoin in Normal Volunteers (Zenith Labs)
1984	Relative Bioavailability of Carbamazepine in Chewable and Conventional Tablets
	(Ciba-Geigy)
1984	Transdermal Delivery of Propranolol (Medtronics)
11/84 - 1/85	Absorption and Metabolism of Carbamazepine in Normal Volunteers (Ciba-Geigy)
1/85 - 4/85	Transdermal Absorption of β-Blockers (Medtronics, Inc.)
11/85 - 4/86	Relative Bioavailability of Sustained Release Oral Dosage Forms of Carbamazepine (Ciba-
, ,	Geigy)
1/86 - 6/86	Analysis of Analgesics in Receptor Media (Medtronics)
8/86 - 12/86	Bioequivalence of Carbamazepine Oral Dosage Forms (Ciba-Geigy)
1/86 - 12/88	Pharmacokinetics of Diltiazem in the Rabbit (Marion)
2/87 - 9/87	Bioequivalence of Carbamazepine Dosage Forms Demonstrating Varying Dissolution Rates
	(Ciba-Geigy)
6/1/87 - 10/15/87	Effect of Urine Flow on the Renal Clearance of Carbamazepine and its Metabolites in
	Humans (Ciba-Geigy)
1/88 - 6/88	Effect of Fasting on the Absorption of Diclofenac Sodium in Normal Human Volunteers
	(Ciba-Geigy)
4/1/89 - 3/31/92	Enhancing Brain Uptake of AZT by Transport Inhibition, (NINCDS / NIH)
7/1/89 - 6/30/90	Induction of Carbamazepine Metabolism as a Function of Dosing Rate in Normal Volunteers
0.104 (104	(Ciba-Geigy)
9/91 - 6/92	Brain Distribution of EAB-515 in the Rabbit (Sandoz, Ltd.)
11/91 - 5/92	In Situ Absorption from Rabbit Intestine (Lederle Laboratories)
3/92 - 8/92	Clinical Studies of the Absorption of an Oral Immunosuppressant (Apotex Laboratories)
11/92 - 10/93	Brain Distribution of an NMDA-Receptor Antagonist in the Rat (Sandoz, Ltd).
10/92 - 5/93	Brain Uptake of a CNS-Active Agent (Warner-Lambert)
11/92 - 3/93	In Situ Absorption from Rabbit Intestine (Lederle Laboratories)
9/94 - 5/95	Population Pharmacokinetic Analysis of A General Anesthetic in Man (Abbott Laboratories)
7/94 - 5/95	Brain Uptake of a Cholinesterase Inhibitor and its Metabolites (Warner-Lambert)
10/94 - 9/95	Distribution of Antiviral Nucleosides into Rat Cortex (Bristol-Myers Squibb)
9/95 - 8/96	Bioanalytical Methods Development of Selected Drugs and Metabolites (MedTox)
1/96-9/96	Pharmacokinetic Analysis of IL-2 in the Pig (Chiron)
1/96 - 6/98	Analysis of Selected Macrolides by High-pressure Liquid Chromatography (TAP)
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4/96-10/97	Brain Penetration of Fosphenytoin and Phenytoin in the Rabbit (Warner-Lambert)
4/96-9/96	Analysis and Brain Uptake of PPI-457 (Pharmaceutical Peptides, Inc)
7/97-3/98	Regional Intestinal Absorption of Anti-CMV agents (Bristol-Myers Squibb)
8/97-6/98	EM574 absorption in the rabbit in situ (TAP)
7/97-9/97	Pharmacokinetics of macrolides in Protocol EM-97-006 (TAP)
11/97-12/97	Drug Interaction Pharmacokinetic Analysis (McNeil)
8/97-3/98	Analysis and Pharmacokinetics of Macrolides in EM-97-008 (TAP)
10/97-12/97	Pharmacokinetics of Slow Release Agents in the CNS (Chiron)
1/98	LC/MS/MS Equipment Grant (TAP)
2/98-12/99	Analysis of Macrolides and Metabolites in EM-97-013 (TAP)
3/98-12/99	Chemical Stability of Selected Agents (Medtronic)
5/98	Validation of Analysis of Macrolides in Dog Plasma (TAP)
8/98	Validation of Analysis of Macrolides in Rabbit Plasma (TAP)
8/98	Stability of anticancer drugs in solution (Medtronic)
8/98	EM574 toxicokinetics in the dog (TAP)
12/98	EM574 toxicokinetics in the rabbit (TAP)
1/99	Pharmacodynamics of EM574 on LES Pressure (protocol 004) (TAP)
3/99	Effect of Time of Dosing on Absorption of EM574 (protocol 007(TAP)
4/99	Effect of Gastric Emptying on the pharmacokinetics of EM574 and its metabolites (protocol 002)
	(TAP)
2/9	Stability of FUDR and heparin in solution (Medtronic)
2/99	Pharmacodynamics and PKs of EM574 and its metabolites during chronic dosing (protocol 029)
	(TAP)
3/00-8/01	Pharmacokinetics of CDTR and distribution to middle ear fluid (TAP)
8/00-6-01	Distribution of ketolides to middle ear fluid (Abbott)
10/01-09/03	Pharmacokinetics of Ketolides (Abbott)
12/01-11/03	Pharmacokinetics and Distribution of cefdinir (Abbott)
12/02-12-03	Effect of a P-Glycoprotein Inhibitor on the Middle Ear Distribution of Clarithromycin (Abbott)
12/02-6-04	Distribution a Cephalosporin into Middle Ear Fluid in Children with Otitis Media (H LaRoche)
12/02-12-04	Development and Testing of Formulations for Delivery of Antibiotics to the Middle Ear (Abbott)
5/03-4/05	A New Approach for the Therapy of Otitis Media (Abbott)
8/04-7/05	Distribution of Macrolide antibiotics to tissue sites (Pfizer)
5/05-11/05	Testing the Distribution of Amoxicillin into Middle Ear Fluid in the Chinchilla following Pulsatile
	Dose Administration (Advancis)
1/06-9-06	Distribution of Macrolide antibiotics to Pulmonary Tissue and Skeletal Muscle (Pfizer)
9/07-10-08	Transtympanic Membrane Delivery of an Antibiotic to the Middle Ear (Alcon)
11/07-12-08	Development of an Acute Otitis Media Middle Ear Microdialysis Model in the Chinchilla with
,	Implanted Tympanostomy Tube (Alcon)

PATENT FILED

United States Patent. Number 7,220,431 "METHODS AND COMPOSITIONS FOR APPLYING PHARMACOLOGIC AGENTS TO THE EAR." UMN Docket # Z01159. RJ Sawchuk and BW Cheung. Issue Date: May 22, 2007. Filing Date: November 27, 2002: #06,306,517

PUBLICATIONS

BOOKS AND CHAPTERS

J. Blanchard, R.J. Sawchuk and B.B. Brodie, Editors. <u>Principles and Perspectives in Drug Bioavailability.</u> S. Karger, Basel, 1979.

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- J. Blanchard and R.J. Sawchuk, "Drug Bioavailability: An Overview" in <u>Principles and Perspectives of Drug Bioavailability</u>, J. Blanchard, R.J. Sawchuk and B.B. Brodie (Editors), S. Karger, Basel, 1979.
- I.E. Leppik, J. Shope, R.J. Sawchuk, W.A. Hauser and B. Van Dyne, "Variability of Antiepileptic Drug Levels During Chronic Therapy" in <u>Epileptology</u>, M. Dam, L. Gram and K. Penry (Editors), Raven Press, NY, 1981.
- R.J. Sawchuk, "Drug Absorption and Disposition in Burn Patients" in <u>The Pharmacokinetic Basis of Drug Treatment</u>, N. Massoud, L.Z. Benet, and J.G. Gambertoglio (Editors), Raven Press, NY, 1984.
- "Use of Microdialysis in Drug Delivery Studies." Theme Issue. W.F. Elmquist and R.J. Sawchuk (Editors) *Advanced Drug Delivery Reviews* 45, Nos. 2-3 (2000).
- R. J. Sawchuk and B.W.Y. Cheung, "Application of Microdialysis in Pharmacokinetic Studies." in <u>Handbook of Microdialysis: Methods, Applications and Clinical Aspects</u>, B.H.C. Westerink and T.I.F.H. Cremers (Editors), Academic Press, Amsterdam, 2007.

PROFESSIONAL PUBLICATIONS

- R.J. Sawchuk, "The Plateau Principle in Drug Therapy. Part 1: The Principle and Its Application." *Minn. Pharmacist* 27(6): 19 (1973).
- R.J. Sawchuk, "The Plateau Principle in Drug Therapy. Part 2: Factors Governing Plateau Levels During Chronic Drug Therapy." *Minn. Pharmacist* 27(7): 8 (1973).
- M.C. Meyer, A.B. Straughn, L.J. Leeson, R.H. Levy and R.J. Sawchuk, "Meprobamate Bioavailability Monograph." *JAPhA* NS17, 173 (1977).
- R.J. Sawchuk and T.S. Rector, "Burn-Induced Alterations in Drug Absorption and Disposition." *Minn. Pharmacist* 35: 6-9 (1981).

SCIENTIFIC PUBLICATIONS (NON-REFEREED)

I.E. Leppik, J. Cloyd and R.J. Sawchuk, "Coefficient of Variation as a Measure of Compliance" Letter. *Lancet*, October 14, 1978.

SCIENTIFIC PUBLICATIONS (REFEREED)

- 1. R.J. Sawchuk, J.M. Anderson and J.G. Nairn. "Stirring apparatus for the investigation of unstable strongly adsorbing chemicals." *J. Pharm. Sci.* 55: 1463 (1966).
- 2. R.J. Sawchuk and J.G. Nairn. "Rate studies on the binding of bilirubin by ion-exchange resins." *J. Pharm. Sci.* 57: 1896 (1968).
- 3. R.J. Sawchuk, J. Robayo and K.W. Miller. "The distribution of propranolol between blood and plasma in hypertensive patients." *Br. J. Clin. Pharmacol.* 1: 440 (1974).
- 4. R.J. Sawchuk and D.E. Zaske. "Pharmacokinetics of dosing regimens which utilize multiple intravenous infusions: gentamicin in burn patients." *J. Pharmacokin. Biopharm.* 4: 183 (1976).
- 5. D.E. Zaske, R.J. Sawchuk, D.N. Gerding and R.G. Strate. "Increased dosage requirements of gentamicin in burn patients." *J. Trauma* 16: (1976).
- 6. R.J. Sawchuk, D.E. Zaske, R.J. Cipolle, W.A. Wargin and R.G. Strate. "Kinetic model for gentamicin dosing with the use of individual patient parameters." *Clin. Pharmacol. Therap.* 21: 362 (1977).

- 7. J.C. Cloyd, D.E. Bosch and R.J. Sawchuk. "Concentration-time profile of phenytoin after admixture with small volumes of intravenous fluids." *Am. J. Hosp. Pharm.* 35: 45-48 (1978).
- 8. J.D. Wirtschafter, C.R. Volk and R.J. Sawchuk. "Trans-aqueous diffusion of acetylcholine to denervated iris sphincter muscle: A hypothetical mechanism for the tonic pupil syndrome (Adie's Syndrome). *Annals of Neurology* 4: 1-5 (1978).
- 9. D.E. Zaske, R.J. Sawchuk and R.G. Strate. "The necessity of increased doses of amikacin in burn patients." *Surgery* 84: 603-608 (1978).
- 10. S.M. Ehlers, D.E. Zaske and R.J. Sawchuk. "Massive theophylline overdose: rapid removal by charcoal memoperfusion. *JAMA* 240: 474 (1978).
- 11. I.E. Leppik, V. Ramani, R.J. Sawchuk and R.J. Gumnit. "Increased clearance of phenytoin during mononucleosis." *NEJM* 300: (1979).
- 12. H.G. McCoy, R.J. Cipolle, S.M. Ehlers, R.J. Sawchuk and D.E. Zaske. "Severe methanol poisoning: application of a pharmacokinetic model for ethanol therapy and hemodialysis." *Am. J. Med.* 67: 804-807 (1979).
- 13. R.J. Sawchuk, T.S. Rector, J.J. Fordice and I.E. Leppik. "Effect of influenza vaccination on plasma phenytoin concentrations." *Therap. Drug Monitoring* 1: 285-288 (1979).
- 14. R.J. Sawchuk and T.S. Rector. "Steady-state plasma concentrations as a function of the absorption rate and dosing interval for drugs exhibiting concentration-dependent clearance: consequences for phenytoin therapy." *J. Pharmacokin. Biopharm.* 7: 543-555 (1979).
- 15. S. Pancorbo, R.J. Sawchuk, C. Dashe and M. Schallock. "Use of a pharmacokinetic model for individualizing intravenous doses of aminophylline." *Eur. J. Clin. Pharmacol.* 16: 251-254 (1979).
- 16. I.E. Leppik, J.C. Cloyd, R.J. Sawchuk and S.M. Pepin. "Compliance and variability of plasma phenytoin levels." *Therap. Drug Monitoring* 1: 475-483 (1979).
- 17. R.L. Kriel, J.C. Cloyd, K.H. Green, R.J. Sawchuk, L.A. Lockman and R. Eggerth. "The pharmacokinetics of valproic acid in children." *Ann. Neurology* 6: 179 (1979).
- 18. R.J. Sawchuk and L.L. Cartier. "Liquid-chromatographic method for simultaneous determination of phenytoin and 5-(4-hydroxyphenyl)-5-phenylhydantoin in plasma and urine." *Clin. Chem.* 26: 835-839 (1980).
- 19. N.K. Kouchenour, M. Emery and R.J. Sawchuk. "Phenytoin absorption and metabolism in pregnancy." *Obstetrics and Gynecology* 56: 577-582 (1980).
- 20. S.E. Chen, R.J. Sawchuk and E.J. Staba. "American ginseng. III. Pharmacokinetics of ginsenosides in the rabbit." *Eur. J. Drug Metab. Pharmacokin.* 5: 161-168 (1980).
- 21. D. Baker, J.C. Rotschafer, R.J. Sawchuk, K.B. Crossley and L.C. Solem. "Vancomycin pharmacokinetics." *J. Pediatr.* 97: 502-503 (1980).
- 22. R.J. Sawchuk* and T.S. Rector. "Drug kinetics in burn patients." Clin. Pharmacokinetics 5: 548-556 (1980).
- 23. G.R. Matzke, J.C. Cloyd and R.J. Sawchuk. "Acute phenytoin and primidone intoxication, a pharmacokinetic analysis." *J. Clin. Pharmacol.* 21: 92-99 (1981).

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- 24. El-Yazigi and R.J. Sawchuk. "Theophylline absorption and disposition in the rabbit: oral, intravenous, and concentration-dependent kinetic studies." *J. Pharm. Sci.* 70: 452-456 (1981).
- 25. J.H. Fischer, J.C. Cloyd, R.L. Kriel, R. Eggerth and R.J. Sawchuk. "The effect of concomitant antiepileptic therapy on valproic acid pharmacokinetics." *Epilepsia* 22: 237 (1981).
- 26. R.J. Sawchuk and L.L. Cartier. "Liquid-chromatographic determination of cyclosporin A in blood and plasma." *Clinical Chemistry* 27: 1368-1371 (1981).
- 27. G.R. Matzke and R.J. Sawchuk. "Elevated serum phenytoin concentrations in a uremic patient when measured by enzyme-multiplied immunoassay." *Drug Intell. Clin. Pharm.* 15: 386-387 (1981).
- 28. R.J. Sawchuk, S.M. Pepin, I.E. Leppik and R.J. Gumnit. "Rapid and slow release phenytoin in epileptic patients at steady state: comparative plasma levels and toxicity." *J. Pharmacokin. Biopharm.* 10: 365-382 (1982).
- 29. R.J. Sawchuk, S.M. Pepin, I.E. Leppik and R.J. Gumnit. "Rapid and slow release phenytoin in epileptic patients at steady state: assessment of relative bioavailability utilizing Michaelis-Menten parameters." *J. Pharmacokin. Biopharm.* 10: 383-391 (1982).
- 30. J. Rotschafer, K. Crossley, D. Zaske, K. Mead, R.J. Sawchuk and L.D. Solem. "Pharmacokinetics of vancomycin: observations in 28 patients and dosage recommendation." *Antimicrob. Ag. Chemother.* 22: 391-394 (1982).
- 31. R.J. Sawchuk and L.L. Cartier. "Liquid-chromatographic method for simultaneous determination of carbamazepine and its epoxide metabolite in plasma." *Clin. Chem.* 28: 2127-2130 (1982).
- 32. W.A. Wargin, R.J. Sawchuk, J.W. McBride, H.G. McCoy and M.L. Rylander. "Variable first-pass elimination of propranolol following single and multiple oral doses in hypertensive patients." *Eur. J. Drug Metab. Pharmacokin.* 7: 183-189 (1982).
- 33. J.C. Cloyd, R.L. Kriel, J.H. Fischer, R.J. Sawchuk and R.M. Eggerth. "Pharmacokinetics of valproic acid in children. I. Multiple antiepileptic drug therapy." *Neurology* 33: 185-191 (1983).
- 34. R.M. Ferguson, R.K. Fidelus, R.J. Sawchuk and K. Gajl. "The mechanism of action of cyclosporine in man." *Transpl. Proc.* 15(1): (1983).
- 35. D.K. Yu and R.J. Sawchuk. "Gas-liquid chromatographic determination of propylene glycol and plasma and urine." *Clin. Chem.* 29: 2088-2090 (1983).
- 36. R.J. Sawchuk and G.R. Matzke. "Contribution of 5-(4-hydroxyphenyl)-5-phenylhydantoin to the discrepancy between phenytoin analyses by EMIT and high pressure liquid chromatography." *Ther. Drug Monit.* 6: 97-103, (1984).
- 37. R.K. Sylvester, B. Lewis, K. Caldwell, M. Lobell, R. Perri and R.J. Sawchuk. "Phenytoin malabsorption secondary to cisplatinum, vinblastine and bleomycin." *Ther. Drug Monit.* 6: 302-305 (1984).
- 38. W. Awni and R.J. Sawchuk. "The pharmacokinetics of cyclosporine. I. Single-dose and constant-rate infusion studies in the rabbit." *Drug Metab. Disposition* 13(2): 127-132 (1984).
- 39. W. Awni and R.J. Sawchuk. "The pharmacokinetics of cyclosporine. II. Blood-plasma distribution and binding studies." *Drug Metab. Disposition* 13(2): 133-138 (1984).

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- 40. K.H. Chan, R.J. Sawchuk, T.A. Thompson, E. Redalieu, W.E. Wagner, Jr., A.R. LeSher, B.J. Weeks, N.R. Hall and A. Gerardin. "Bioequivalence of carbamazepine chewable and conventional tablets: single dose of steady-state studies." *J. Pharm. Sci.* 74(8): 866-870 (1985).
- 41. A. El-Yazigi and R.J. Sawchuk. "In vitro in vivo correlation and dissolution studies with oral theophylline dosage forms." J. Pharm. Sci. 74(2): 161-164 (1985).
- 42. D.K. Yu, W.F. Elmquist and R.J. Sawchuk. "Pharmacokinetics of propylene glycol in humans during multiple dosing regimens." *J. Pharm. Sci.* 74(8): 876-878 (1985).
- 43. R.J. Sawchuk and W. Awni. "Absorption of cyclosporine from rabbit small intestine *in situ*." *J. Pharm. Sci.* 75(12): 1151-1156 (1986).
- 44. G.R. Matzke, R.C. Brundage and R.J. Sawchuk. "Protein binding of phenytoin, p-hydroxyphenytoin, and p-hydroxy phenytoin glucuronide." *J. Clin. Pharmacol.* 26: 677-679 (1986).
- 45. R.M. Ferguson, D.M. Canafax, R.J. Sawchuk and Simmons R.L. Cyclosporine blood level monitoring: the early posttransplant period. *Transplantation Proceedings*. 18(2 Suppl 1):113-22, (1986).
- 46. C. Fletcher, R.J. Sawchuk, B. Chinnock, P. de Miranda and H.H. Balfour. "Human pharmacokinetics of the antiviral drug DHPG." *Clin. Pharmacol. Therap.* 40: 281-286 (1986).
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- 54. L.E. Riad and R.J. Sawchuk. "Determination of the relative formation of elimination clearance of carbamazepine metabolites in humans: a comparison of traditional and pooled sample analysis." Third European Congress of Biopharmaceutics and Pharmacokinetics, Freiburg, Germany, April 21, 1987.

- 55. W.F. Elmquist, D.K. Yu, G. Solis and R.J. Sawchuk. "Physiological modelling of the dependence of renal clearance on urine flow: propylene glycol pharmacokinetics in man." Third European Congress of Biopharmaceutics and Pharmacokinetics, Freiburg, Germany, April 21, 1987.
- 56. A.K. Shah, K.D. Lake and R.J. Sawchuk. "Blood levels of cyclosporine A and its metabolites in rabbit and man." American Association of Pharmaceutical Scientists Annual Meeting, Boston, MA, June 1987.
- 57. K.D. Lake, Pharm.D.*, A.K. Shah, Ph.D., R. Emery, M.D. and R.J. Sawchuk, Ph.D. "Measurement of cyclosporine metabolites in the blood of heart transplant recipients." American College of Clinical Pharmacy Annual Meeting, May 1987.
- 58. A.K. Shah, A. Gratwohl and R.J. Sawchuk. "Subcutaneous absorption of cyclosporine in rabbits." 2nd International Congress on Cyclosporine, Washington, DC, November 4-7, 1987.
- 59. M.A. Hedaya and R.J. Sawchuk. "The effect of probenecid on the renal excretion of azidothymidine (AZT) in the rabbit." Third Annual Meeting, AAPS, Orlando, FL, October 29-November 4, 1988.
- 60. W.F. Elmquist, K.K.H. Chan, V.A. John and R.J. Sawchuk. "Transsynovial distribution of diclofenac." Third Annual Meeting, AAPS, Orlando, FL, October 29-November 4, 1988.
- 61. L.E. Riad and R.J. Sawchuk. "Administration of site-related differences in carbamazepine disposition in the rabbit." Third Annual Meeting, AAPS, Orlando, FL, October 29-November 4, 1988.
- 62. A.K. Shah and R.J. Sawchuk. "Effect of urine flow on the renal clearance of cyclosporine in rabbit." Third Annual Meeting, AAPS, Orlando, FL, October 29-November 4, 1988.
- 63. W.F. Elmquist, L.E. Riad, I.E. Leppik and R.J. Sawchuk. "Physiological modelling of the dependence of renal clearance on urine flow: carbamazepine and two metabolites in man." Third Annual Meeting, AAPS, Orlando, FL, October 29-November 4, 1988.
- 64. M.A. Hedaya and R.J. Sawchuk. "Pharmacokinetic analysis of the enhanced distribution of zidovudine into rabbit cerebrospinal fluid caused by probenecid." V. International Conference on AIDS, Montreal, June 4-9, 1989.
- 65. Y. Wang, M.A. Hedaya and R.J. Sawchuk. "Effect of mannitol IV infusion on distribution of zidovudine between plasma and cerebrospinal fluid in rabbits." V. International Conference on AIDS, Montreal, June 4-9, 1989.
- 66. M.A. Hedaya, W.F. Elmquist and R.J. Sawchuk. University of Minnesota, Minnesota, Minnesota, USA. "Probenecid inhibits the metabolic and renal clearances of zidovudine in human volunteers." V. International Conference on AIDS, Montreal, June 4-9, 1989.
- 67. M.A. Hedaya and R.J. Sawchuk. "A sensitive and specific HPLC method for the determination of zidovudine and zidovudine glucuronide in plasma and urine." V. International Conference on AIDS, Montreal, June 4-9, 1989.
- 68. M.A. Hedaya and R.J. Sawchuk. "A simple and specific liquid-chromatographic method for determination of ganciclovir (DHPG) in plasma and urine." Fourth Annual Meeting, AAPS, Atlanta, GA, October 21-26, 1989.
- 69. L.E. Riad and R.J. Sawchuk. "Intestinal absorption of carbamazepine in the rabbit." Fourth Annual Meeting, AAPS, Atlanta, GA, October 21-26, 1989.

- 70. A.J. Shah and R.J. Sawchuk. "The effect of altering blood lipids on the pharmacokinetics of cyclosporine in the rabbit." Fourth Annual Meeting, AAPS, Atlanta, GA, October 21-26, 1989.
- 71. M.A. Hedaya, W.F. Elmquist and R.J. Sawchuk. "Mechanism of zidovudine (AZT) dose-sparing by probenecid in humans." Fourth Annual Meeting, AAPS, Atlanta, GA, October 21-26, 1989.
- 72. W.F. Elmquist and R.J. Sawchuk. "Tissue mean transit time determination from steady-state partition coefficients and tissue/plasma concentration ratios in the post-distributive phase." Fourth Annual Meeting, AAPS, Atlanta, GA, October 21-26, 1989.
- 73. L.E. Riad and R.J. Sawchuk. "Relative bioavailability and effects of food on plasma levels of diclofenac sodium following a single oral dose of Voltaren 100-mg SR tablet." Fourth Annual Meeting, AAPS, Atlanta, GA, October 21-26, 1989.
- 74. O.H. Chan and R.J. Sawchuk. "Intestinal absorption of diltiazem in the rabbit." Fourth Annual Meeting, AAPS, Atlanta, GA, October 21-26, 1989.
- 75. R.J. Sawchuk. "Pharmacokinetic and analytical considerations in monitoring zidovudine (AZT) levels in children with AIDS." The Fourth International Congress on Pediatric Laboratory Medicine, Washington, DC, August 23, 1989.
- 76. K.D. Lake, A.K. Shah, R.W. Emery, D.R. Holder and R.J. Sawchuk. "The effect of urine flow rate on the renal clearance of cyclosporine in heart transplant recipients." International Society for Heart Transplantation, Tenth Annual Meeting, Fort Lauderdale, FL, April 4-6, 1990.
- 77. R.J. Sawchuk. "Effect of temperature and medium of analysis on CsA concentration." Canadian Consensus Meeting on Cyclosporine Monitoring, Minaki Lodge, Ontario, May 10-13, 1990.
- 78. H. Das, S.W. Wong, K. Chan, R.J. Sawchuk and R.L. Oberle. "Pharmacokinetics and metabolism of diclofenac sodium (Voltaren) after IV and oral administration to Yucatan miniswine." Eastern Regional AAPS meeting, New Brunswick, NJ, June 3-5, 1990.
- 79. S.M. Wong and R.J. Sawchuk. "Interaction of zidovudine and probenecid at steady state." NATO Advanced Study Institute Symposium "New Trends in Pharmacokinetics." Erice, Sicily, September 4-15, 1990.
- 80. W.F. Elmquist and R.J. Sawchuk. "Tissue mean transit time determination from steady-state partition coefficients and tissue/plasma concentration ratios in the postdistributive phase." NATO Advanced Study Institute Symposium "New Trends in Pharmacokinetics," Erice, Sicily, September 4-15, 1990.
- 81. A.K. Shah, R.J. Sawchuk, A. Gratwohl and R.C. Brundage. "Modeling subcutaneous absorption of cyclosporine A in rabbits." NATO Advanced Study Institute Symposium "New Trends in Pharmacokinetics," Erice, Sicily, September 4-15, 1990.
- 82. L.E. Riad, K.K.H. Chan and R.J. Sawchuk. "Effects of dosing rate on carbamazepine enzymatic induction in normal volunteers." NATO Advanced Study Institute Symposium "New Trends in Pharmacokinetics," Erice, Sicily, September 4-15, 1990.
- 83. W.F. Elmquist, L.E. Riad, I.E. Leppik and R.J. Sawchuk. "The relationship between carbamazepine urine and plasma concentrations: implications for therapeutic drug monitoring." AAPS Fifth Annual Meeting, Las Vegas, NV, November 4-8, 1990.
- 84. S.M. Wong, L.E. Riad, P. Degen, V. John, K. Chan and R.J. Sawchuk. "Comparison of plasma concentrations of diclofenac sodium and its metabolites during single and multiple dosing of Voltaren SR tablet in humans." AAPS Fifth Annual Meeting, Las Vegas, NV, November 4-8, 1990.

- 85. O.H. Chan and R.J. Sawchuk. "Saturable first-pass elimination of diltiazem during intestinal absorption in the rabbit." AAPS Fifth Annual Meeting, Las Vegas, NV, November 4-8, 1990.
- 86. L.E. Riad and R.J. Sawchuk. "Carbamazepine enzymatic induction: extent and effects of dosing rate in normal volunteers." AAPS Fifth Annual Meeting, Las Vegas, NV, November 4-8, 1990.
- 87. Y.-F. Wang, M.A. Hedaya and R.J. Sawchuk. "Comparative absorption and disposition pharmacokinetics of AZT and AZddU in rabbits." AAPS Fifth Annual Meeting, Las Vegas, NV, November 4-8, 1990.
- 88. S.L. Wong and R.J. Sawchuk. "Investigation of distribution of zidovudine into the brain by microdialysis." AAPS Fifth Annual Meeting, Las Vegas, NV, November 4-8, 1990.
- 89. S.L. Wong and R.J. Sawchuk. "Interaction of zidovudine and probenecid at steady state." AAPS Fifth Annual Meeting, Las Vegas, NV, November 4-8, 1990.
- 90. S.L. Wong, Y.-F. Wang and R.J. Sawchuk. "Brain/plasma distribution kinetics of zidovudine (AZT) in the rabbit using microdialysis." 1991 Symposium on Microdialysis and Allied Analytical Techniques, Indianapolis, IN, May 16-17, 1991.
- 91. K. Van Belle, S.L. Wong, Y.-F. Wang and R.J. Sawchuk. "Comparative delivery and distribution kinetics of zidovudine (AZT) and AZddU into the rabbit brain by microdialysis." 1991 Symposium on Microdialysis and Allied Analytical Techniques, Indianapolis, IN, May 16-17, 1991.
- 92. Y.-F. Wang, S.L. Wong and R.J. Sawchuk "In vitro and in vivo calibration of microdialysis probes using retrodialysis." 1991 Symposium on Microdialysis and Allied Analytical Techniques, Indianapolis, IN, May 16-17, 1991.
- 93. B.W. Cheung, L.E. Riad and R.J. Sawchuk. "Comparative uptake of selected anticonvulsant drugs into rabbit brain." 1991 Symposium on Microdialysis and Allied Analytical Techniques, Indianapolis, IN May 16-17, 1991.
- 94. L.E. Riad, K.K. Chan, J.A. Maloney and R.J. Sawchuk. "Reversibility of carbamazepine autoinduction upon dose termination in normal volunteers." AAPS Sixth Annual Meeting, Washington, DC, November 17-21, 1991.
- 95. S.L. Wong, M.A. Hedaya and R.J. Sawchuk. "Modeling the competitive inhibition of renal and nonrenal clearance of zidovudine by probenecid." AAPS Sixth Annual Meeting, Washington, DC, November 17-21, 1991.
- 96. K. Van Belle, S.L. Wong, Y.-F. Wang and R.J. Sawchuk. "Comparison of pharmacokinetics and CNS distribution of coadministered AZT and AZddU by microdialysis." AAPS Sixth Annual Meeting, Washington, DC, November 17-21, 1991.
- 97. Y.-F. Wang, S.L. Wong and R.J. Sawchuk. "*In vitro* and *in vivo* calibration of microdialysis probes using retrodialysis: application to the study of brain/plasma distribution of zidovudine." AAPS Sixth Annual Meeting, Washington, DC, November 17-21, 1991.
- 98. W.F. Elmquist, L.E. Riad, I.E. Leppik and R.J. Sawchuk. "The relationship between urine and plasma concentrations of carbamazepine and phenytoin in epileptic patients on chronic therapy." AAPS Sixth Annual Meeting, Washington, DC, November 17-21, 1991.
- 99. S.L. Wong, Y.-F. Wang, and R.J. Sawchuk. "Effect of dose on distribution of zidovudine (AZT) into rabbit brain using microdialysis with *in vivo* calibration." AAPS Sixth Annual Meeting, Washington, DC, November 17-21, 1991.

- 100. W.F. Elmquist, I.E. Leppik and R.J. Sawchuk. "Physiological modeling of the dependence of renal clearance on urine flow II: phenytoin and HPPH in humans." American Association of Pharmaceutical Scientists Annual Meeting, Washington, DC, November 17-21, 1991.
- 101. R.J. Sawchuk. "Study of zidovudine distribution into the CNS utilizing microdialysis." 25th Annual Higuchi Research Seminar, Lake of the Ozarks, MO, March 8-11, 1992.
- 102. Y.F. Wang and R.J. Sawchuk. "Microdialysis studies of brain/plasma distribution of AZT during intraventricular and intravenous infusion." AAPS Seventh Annual Meeting, San Antonio, TX, November 15-19, 1992.
- 103. S.L. Wong, K. Van Belle, and R.J. Sawchuk. "A microdialysis study of probenecid's effect on the transport kinetics of zidovudine in rabbit brain." AAPS Seventh Annual Meeting, San Antonio, TX, November 15-19, 1992.
- 104. S.L. Wong, and R.J. Sawchuk. "Pharmacokinetic interaction of zidovudine and salicylic acid during continuous infusion." AAPS Seventh Annual Meeting, San Antonio, TX, November 15-19, 1992.
- 105. S.L. Wong, and R.J. Sawchuk. "Effect of salicylic acid on the distribution of zidovudine between plasma and cerebrospinal fluid." AAPS Seventh Annual Meeting, San Antonio, TX, November 15-19, 1992.
- 106. R.C. Brundage, K.K.H. Chan, and R.J. Sawchuk. "Population pharmacokinetic modeling of nicotine following transdermal drug administration." AAPS Seventh Annual Meeting, San Antonio, TX, November 15-19, 1992.
- 107. R.C. Brundage, K.K.H. Chan, and R.J. Sawchuk. "Population pharmacokinetics of diclofenac potassium using routinely collected experimental data." AAPS Seventh Annual Meeting, San Antonio, TX, November 15-19, 1992.
- 108. W.F. Elmquist and R.J. Sawchuk. "Simulation of the effect that the time delay in sampling from the bladder has on urine concentrations: implications for therapeutic drug monitoring using urine specimens." AAPS Seventh Annual Meeting, San Antonio, TX, November 15-19, 1992.
- 109. J.P. Zhong, Y.F. Wang and R.J. Sawchuk. "Absorption of three antiviral nucleosides from different anatomic regions of rabbit intestine." AAPS Seventh Annual Meeting, San Antonio, TX, November 15-19, 1992.
- 110. Y.F. Wang, S.L. Wong, and R.J. Sawchuk. "On-line microdialysis calibration using retrodialysis and the zero-net flux method: application to a study of the distribution of AZT to rabbit CSF and thalamus." AAPS Seventh Annual Meeting, San Antonio, TX, November 15-19, 1992.
- 111. R.J. Sawchuk. "Comparative distribution of AZT into brain tissue extracellular fluid during intravenous and intraventricular infusion using microdialysis." 26th Annual Higuchi Research Seminar, Lake of the Ozarks, MO, March 14-17, 1993.
- 112. Y. Wang and R.J. Sawchuk, "Comparison of renal clearance of AZdU following IV bolus and constant-rate Infusion." 8th Annual Meeting, American Association of Pharmaceutical Scientists, Orlando, FL, November 14-18, 1993.
- 113. Y. Wang and R.J. Sawchuk. "Assessment of oral absorption of AZT and AZdU in the rabbit using deconvolution." 8th Annual Meeting, American Association of Pharmaceutical Scientists, Orlando, FL, November 14-18, 1993.

- 114. Y. Wang, Y. Wei and R.J. Sawchuk. "Microdialysis studies of carrier-mediated transport of AZT from brain to plasma during intracerebroventricular infusion." 8th Annual Meeting, American Association of Pharmaceutical Scientists, Orlando, FL, November 14-18, 1993.
- 115. B.K. Malhotra, M. Lemaire, and R.J. Sawchuk. "Investigation of the CNS distribution of EAB 515 in freely moving rats by microdialysis." 8th Annual Meeting, American Association of Pharmaceutical Scientists, Orlando, FL, November 14-18, 1993.
- 116. A.K. Shah, R.C. Brundage, K.D. Lake and R.J. Sawchuk. "Estimation of plasma free fraction (fu) of cyclosporine (CYA) in the rabbit and heart transplant (HT) patients by NONMEM using a physiological model of renal clearance (CLr)." 8th Annual Meeting, American Association of Pharmaceutical Scientists, Orlando, FL, November 14-18, 1993.
- 117. B.K. Malhotra, R.C. Brundage, M. Lemaire, and R.J. Sawchuk. "Modeling of the CNS distribution of EAB 515 following IV and ICV administration." 5th Symposium: Frontiers of Pharmacokinetics and Pharmacodynamics, Baltimore, MD, April 18-20, 1994.
- 118. R.C. Brundage, B.K. Malhotra, J.A. Maloney and R.J. Sawchuk. "Brain distribution of tacrine and the 1-hydroxy and 2-hydroxy tacrine metabolites determined by microdialysis in freely-moving rats." 5th Symposium: Frontiers of Pharmacokinetics and Pharmacodynamics, Baltimore, MD, April 18-20, 1994.
- 119. Y. Wang and R.J. Sawchuk. "CNS Distribution of inulin-[¹⁴C]-carboxylic acid in rabbits." 9th Annual Meeting, American Association of Pharmaceutical Scientists, San Diego, CA, November 6-10, 1994.
- 120. B.K. Malhotra, R.C. Brundage and R.J. Sawchuk. "Simultaneous microdialysis of portal and jugular blood following IV bolus and oral lavage in freely-moving rats." 9th Annual Meeting, American Association of Pharmaceutical Scientists, San Diego, CA, November 6-10, 1994.
- 121. R.C. Brundage, B.K. Malhotra, J.A. Maloney and R.J. Sawchuk. "Brain distribution of tacrine and its 1-and 2-hydroxylated metabolites determined by microdialysis in freely-moving rats." 9th Annual Meeting, American Association of Pharmaceutical Scientists, San Diego, CA, November 6-10, 1994.
- 122. B.K. Malhotra, R.C. Brundage, Y. Wang and R.J. Sawchuk. "Dialysis membrane-limited and aqueous boundary layer-limited *in vitro* microdialysis recovery." 9th Annual Meeting, American Association of Pharmaceutical Scientists, San Diego, CA, November 6-10, 1994.
- 123. B.W.Y. Cheung, Y. Wang and R.J. Sawchuk. "Preliminary studies of effects of hydroxy-propyl-beta-cyclodextrin on carbamazepine distribution into rabbit brain." 9th Annual Meeting, American Association of Pharmaceutical Scientists, San Diego, CA, November 6-10, 1994.
- 124. R.J. Sawchuk, J.A. Maloney, L.L. Cartier, R.J. Rackley, K.K.H. Chan and H.S.H. Lau. "Analysis of diclofenac and four of its metabolites in human urine by HPLC." 9th Annual Meeting, American Association of Pharmaceutical Scientists, San Diego, CA, November 6-10, 1994.
- 125. R.C. Brundage, M. Lemaire and R.J. Sawchuk. "Modeling of the CNS distribution of EAB 515 following IV and ICV administration." 9th Annual Meeting, American Association of Pharmaceutical Scientists, San Diego, CA, November 6-10, 1994.
- 126. B.K. Malhotra, M. Lemaire, J.F. Brouillard and R.J. Sawchuk. "High-performance liquid chromatographic (HPLC) analysis of EAB 515 in brain and blood microdialysate (on-line) and in plasma ultrafiltrate of freely-moving rats." 10th Annual Meeting, American Association of Pharmaceutical Scientists, Miami Beach, FL, November 5-9, 1995.

- 127. R.J. Sawchuk, R.C. Brundage, E.D. Kharasch and M.D. Karol. "Physiological-based pharmacokinetic (PBPK) modeling of sevoflurane, a volatile anesthetic." 10th Annual Meeting, American Association of Pharmaceutical Scientists, Miami Beach, FL, November 5-9, 1995.
- 128. R.C. Brundage, S. Thomas Forgue and R.J. Sawchuk. "Comparative distribution of a series of aminoacridines of varying polarities into rat cortex using microdialysis." 10th Annual Meeting, American Association of Pharmaceutical Scientists, Miami Beach, FL, November 5-9, 1995.
- 129. Z. Yang, R.C. Brundage, L.L. Cartier, J.A. Maloney and R.J. Sawchuk. "Development of a microdialysis method to study brain distribution of stavudine (d4t) in freely-moving rats." 10th Annual Meeting, American Association of Pharmaceutical Scientists, Miami Beach, FL, November 5-9, 1995.
- 130. B.K. Malhotra, R.C. Brundage and R.J. Sawchuk. "Estimation of presystemic disposition of drugs based upon combination of area ratios and deconvolution." 10th Annual Meeting, American Association of Pharmaceutical Scientists, Miami Beach, FL, November 5-9, 1995.
- 131. M.A. Osman, R. J. Sawchuk, and M.K. Youssef. "In Situ Absorption of the Antiviral drug, stavudine, from the rabbit intestine." European Symposium on Formulation of Poorly Available Drugs for Oral Administration, Paris, February 5-6, 1996.
- 132. M.A. Osman, R.J. Sawchuk, and M.K. Youssef. "Ganciclovir (DHPG), an antiviral nucleoside that exhibits high absorptive clearance in the rabbit colon *in situ*." European Symposium on Formulation of Poorly-available Drugs for Oral Administration, Paris, February 5- 6, 1996.
- 133. B. K. Malhotra, M. Lemaire, J.F. Brouillard, and R.J. Sawchuk. "High-performance liquid chromatographic (HPLC) analysis of EAB 515 in brain and blood microdialysate (on-line) and in plasma ultrafiltrate of freely-moving rats." 11th Annual Meeting, American Association of Pharmaceutical Scientists, Miami Beach, FL, October 29-31, 1996.
- 134. R.J. Sawchuk, R.C. Brundage, E.D. Kharasch, and M.D. Karol. "Physiologically-based pharmacokinetic (PBPK) modeling of sevoflurane, a volatile anesthetic." 11th Annual Meeting, American Association of Pharmaceutical Scientists, Miami Beach, FL, October 29-31, 1996.
- 135. R.C. Brundage, S.T. Forgue, and R.J. Sawchuk. "Comparative distribution of a series of aminoacridines of varying polarities into rat cortex using microdialysis." 11th Annual Meeting, American Association of Pharmaceutical Scientists, Miami Beach, FL, October 29-31, 1996.
- 136. Z. Yang, R.C. Brundage, L.L. Cartier, J.A. Maloney, and R.J. Sawchuk. "Development of a microdialysis method to study brain distribution of stavudine (d4T) in freely-moving rats." 11th Annual Meeting, American Association of Pharmaceutical Scientists, Miami Beach, FL, October 29-31, 1996.
- 137. B.K. Malhotra, R. C. Brundage, and R. J. Sawchuk. "Estimation of presystemic disposition of drugs based upon combination of area ratios and deconvolution." 11th Annual Meeting, American Association of Pharmaceutical Scientists, Miami Beach, FL, October 29-31, 1996.
- 138. Z. Yang and R.J. Sawchuk. "A modified solvent drag model and its application in studying intestinal absorption of polar drugs." 12th Annual Meeting, American Association of Pharmaceutical Scientists, Boston, MA, November 2-6, 1997.
- 139. Z. Yang and R.J. Sawchuk. "Estimating the intestinal absorptive clearance of drugs: consideration of water absorption during in situ single-pass perfusion studies." 12th Annual Meeting, American Association of Pharmaceutical Scientists, Boston, MA, November 2-6, 1997.

- 140. Z. Yang, P. Manitpisitkul, F.P. LaCreta, C.K. Knupp, R.H. Barbhaiya, and R.J. Sawchuk. "In situ studies of the regional absorption of lobucavir and ganciclovir from rabbit intestine." American Association of Pharmaceutical Scientists Annual Meeting, San Francisco, CA, November 15-19, 1998.
- 141. Z. Yang, Y. Huang, G. Gan, and R.J. Sawchuk. "Microdialysis evaluation of the brain distribution of stavudine following intranasal administration." American Association of Pharmaceutical Scientists Annual Meeting, San Francisco, CA, November 15-19, 1998.
- 142. Z Yuan, P. Ji, S. Giebink, and R.J. Sawchuk. "Antibiotic Middle Ear Pharmacokinetics by Microdialysis." American Association of Pharmaceutical Scientists Annual Meeting, San Francisco, CA, November 15-19, 1998.
- 143. R.J. Sawchuk, P. Ji, Y. Huang. "Distribution of Amoxicillin to Middle Ear Fluid Using Microdialysis Sampling." Higuchi Research Seminar, Lake of the Ozarks, MO, March 14-17, 1999.
- 144. Y. Huang, and R.J. Sawchuk. "Antibiotic Pharmacokinetics in Chinchilla Middle Ear using Microdialysis." Association of Pharmaceutical Scientists Midwest Regional Meeting, Chicago, IL, May 17, 1999
- 145. R.J. Sawchuk, P. Ji, Y. Huang, and S. Giebink. "Kinetics of Transport of Antibiotics to Middle Ear Fluid Using Microdialysis Sampling." Seventh International Symposium on Recent Advances in Otitis Media, Fort Lauderdale, FL, June 1-5, 1999.
- 146. G. Gan, and R.J. Sawchuk. "Intestinal Absorption and Pre-Systemic First Pass Elimination of Minocycline and Propranolol in Rabbits" *American Association of Pharmaceutical Scientists Annual Meeting*, New Orleans, LA, November 14-18, 1999.
- 147. B.W.Y. Cheung, L.L. Cartier, H. Q. Russlie, and R.J. Sawchuk. "Using Sample Pooling Methods in the Determination of AUC and AUMC in Pharmacokinetic Studies" *American Association of Pharmaceutical Scientists Annual Meeting*, New Orleans, LA, November 14-18, 1999.
- 148. Y. Huang, L.L. Cartier, and R.J. Sawchuk. "Analysis of Clarithromycin by Chemiluminescence: In Vitro/InVivo Microdialysis Studies" *American Association of Pharmaceutical Scientists Annual Meeting*, New Orleans, LA, November 14-18, 1999.
- 149. P. Guo, P. Ji, B.W.Y. Cheung, J.B. McCarthy, and R.J. Sawchuk. "Fibronectin Peptide (FN C/H V-Y) Assay and Stability in Human and Rat Plasma" *American Association of Pharmaceutical Scientists Annual Meeting*, New Orleans, LA, November 14-18, 1999.
- 150. R. J. Sawchuk, B. W. Y. Cheung, L. L. Cartier, H. Q. Russlie, T. Zhu, Y. Huang, G. S. Giebink, D. Mulford and M. Mayer. "Kinetics oOf Cefditoren Distribution to Middle Ear Fluid in The Unanesthetized Chinchilla" 40th Interscience Conference on Antimicrobial Agents and Chemotherapy. Toronto, ON, September 17-20, 2000
- 151. G.S. Giebink, T.M. Sheehy, M. Quartey, R.J. Sawchuk, M. Mayer Cefditoren Pharmacodynamics for Streptococcus Pneumoniae (Pnc) Acute Otitis Media (AOM) in the Chinchilla Model" 40th Interscience Conference on Antimicrobial Agents and Chemotherapy. Toronto, ON, September 17-20, 2000.
- 152. Y. Huang, R. J. Sawchuk. "Studies of the Middle Ear Distribution Kinetics of Amoxicillin in the Awake Chinchilla Using Microdialysis". *American Association of Pharmaceutical Scientists Annual Meeting*, Indianapolis, IN, October 29- November 2, 2000.
- 153. J.Z. Peng, R.C. Brundage, and R.J. Sawchuk. "Study of Presystemic Elimination of 4-monomethylamino-antipyrine (MAAP) after Consecutive Doses in Freely Moving Rats Using On-line

- Microdialysis". American Association of Pharmaceutical Scientists Annual Meeting, Indianapolis, IN, October 29- November 2, 2000.
- 154. T. Zhu, Y. Huang, L.L. Cartier, R. J. Sawchuk "In Vitro Microdialysis and Protein Binding Studies of Cefditoren" *American Association of Pharmaceutical Scientists Annual Meeting*, Indianapolis, IN, October 29- November 2, 2000.
- 155. G. Gan, L. L. Cartier, Y. Huang, Z. Yang, R. J. Sawchuk "Intestinal Absorption and Presystemic Elimination of the Prokinetic Agent, EM574, in Rabbits" *American Association of Pharmaceutical Scientists Annual Meeting*, Indianapolis, IN, October 29- November 2, 2000.
- 156. L. C. Musib, J. C. Cloyd, A.K. Birnbaum, T. J. Hietpas, R. J. Sawchuk, I. E. Leppik, T. R. Browne, S. F. Holloway, G. S. Holden, J. O. Rarig. "Preliminary Report on Phenytoin Bioavailability in the Elderly Using an Intravenous Stable-Labeled Isotope". *American Association of Pharmaceutical Scientists Annual Meeting*, Indianapolis, IN, October 29- November 2, 2000.
- 157. Z. Yang, L. M. Zadjura, C. J. D'Arienzo, D. B. Wang-Iverson, R. J. Sawchuk "Use of Sample Pooling in Drug Discovery to Screen for Pharmacokinetic Properties of Compounds in Rats" *American Association of Pharmaceutical Scientists Annual Meeting*, Indianapolis, IN, October 29- November 2, 2000.
- 158. R.J. Sawchuk, Y. Huang, P. Ji, M. Quartey, G.S. Giebink. "Influx/Eflux Penetration Clearance of Amoxicillin between Plasma and Middle Ear Fluid in Freely Moving Chinchillas using Microdialysis" 4th Extraordinary International Symposium on Recent Advances in Otitis Media, Sendai, Japan, April 16-20, 2001.
- 159. T. Zhu, B. W. Cheung, L.L. Cartier, G. S. Giebink, D.J. Mulford, M.D. Mayer, R.J. Sawchuk. "Study of Cefditoren Distribution Kinetics to Middle Ear Fluid in Freely-moving Chinchillas Using Microdialysis." *American Association of Pharmaceutical Scientists Annual Meeting*, Denver, CO, October 21-25, 2001.
- 160. W. Liu, B.W. Cheung, L.L. Cartier, T. Zhu, M.M. Paris, R.J. Sawchuk. "In vitro/In vivo Microdialysis and Protein Binding Studies of the ketolide antibiotic, ABT-773." *American Association of Pharmaceutical Scientists Annual Meeting*, Denver, CO, October 21-25, 2001.
- 161. Y. Huang, R.J. Sawchuk. "Estimation of Amoxicillin Influx and Efflux Clearance between Plasma and Middle Ear Fluid Following Simultaneous Systemic and Local Ear Doses in Awake Chinchilla Using Microdialysis." *American Association of Pharmaceutical Scientists Annual Meeting*, Denver, CO, October 21-25, 2001.
- 162. J.Z. Peng, R.C. Brundage, R.J. Sawchuk. "The Influence of Drug Pre-exposure on First-pass Metabolism of Tacrine in Rats." *American Association of Pharmaceutical Scientists Annual Meeting*, Denver, CO, October 21-25, 2001.
- 163. J.Peng, R.J.Sawchuk, and <u>R.P.Remmel</u> "Mechanism-based inactivation of CYP1A2 by tacrine" 11th North American Meeting of the International Society for the Study of Xenobiotics, Orlando, FL. October 27-31, 2002.
- 164. Y.Song, L.L.Cartier, B.W Cheung, R J Sawchuk. "An Animal Model for Multi-site CSF Disposition Studies of Intrathecally Administered Agents". *American Association of Pharmaceutical Scientists Annual Meeting*, Toronto, Ontario, Canada. November 10-14, 2002.

- 165. J.Z.Peng, R.Remmel, R.J.Sawchuk. "Modeling And Simulation Of In Vivo PK Profiles Based On Mechanism-based Inhibition From In Vitro Studies: Inactivation Of CYP1A2 by Tacrine" American Association of Pharmaceutical Scientists Annual Meeting, Toronto, Ontario, Canada. November 10-14, 2002.
- 166. Y.Song, L.L.Cartier, B. Cheung, R.J. Sawchuk. "Multi-site CSF Disposition Studies of Intrathecally Administered Antiviral Nucleosides in a Novel Animal Model". 8th International Meeting of the International Society for the Study of Xenobiotics, Dijon France. April 27-31, 2003
- 167. W. Liu, B. W. Y. Cheung, R. J. Sawchuk. "Distribution Kinetics of Cethromycin in the Chinchilla Middle Ear". 8th International Symposium on Recent Advances in Otitis Media. Fort Lauderdale, FL. June 3 7, 2003
- 168. P Ji, L Cartier, B W Y Cheung, R J Sawchuk. "Distribution Kinetics Of Cefdinir Between Plasma And Middle Ear Fluid In The Freely Moving Chinchillas". *American Association of Pharmaceutical Scientists Annual Meeting*, Salt Lake City, UT. October 26-30, 2003.
- 169. W. Liu, B. W. Y. Cheung, R J Sawchuk. "Efflux Transport Of Cethromycin Following Direct Intra-bulla Dosing In The Chinchilla Middle Ear". *American Association of Pharmaceutical Scientists Annual Meeting*, Salt Lake City, UT. October 26-30, 2003.
- 170. Y. Song and R. J. Sawchuk. "Pharmacokinetics of Zidovudine and Stavudine in the Cerebrospinal Fluid after Intrathecal Administration in a Novel Rabbit Model". *American Association of Pharmaceutical Scientists Annual Meeting*, Baltimore, MD. November 8, 2004.
- 171. N. Mostafa and R. J. Sawchuk. "Determination of Ofloxacin Clearance from the Middle Ear Fluid using Microdialysis". *American Association of Pharmaceutical Scientists Annual Meeting*, Nashville, TN. November 7, 2005.
- 172. Z. Li, B. W. Y. Cheung, L. Cartier, and R. J. Sawchuk. "The Possible Role of P-glycoprotein in the Distribution of Clarithromycin to the Middle Ear". *American Association of Pharmaceutical Scientists Annual Meeting*, Nashville, TN. November 7, 2005.
- 173. R. J. Sawchuk, L. M. Page, and R. L. Rauck. "Pharmacokinetics of Gabapentin Injection in Cerebrospinal Fluid and Plasma with Intrathecal Administration". FDA Science Forum, Washington, DC. April 18, 2006.
- 174. R. J. Sawchuk . "Bugs and Drugs: Does the Anti-infective Agent get to the Target Site?" *American Pharmacists Association Annual Meeting*, Atlanta, GA. March 18, 2007.
- 175. R. J. Sawchuk. "Future Perspectives on the Contributions of Microdialysis in Drug Research and Development" Fifth International Symposium on Microdialysis in Drug Research and Development. Leiden, NE. April 25, 2007.
- 176. R.J. Sawchuk. "Drug Delivery to the Middle Ear across the Tympanic Membrane for Therapy of Acute Otitis Media". Global Gators 6th Symposium on Clinical Pharmacy and Clinical Pharmacology. Munich, Germany. June 9, 2007.

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- 177. T. Wang, R. J. Sawchuk and W. F. Elmquist. "Modeling Distributional Kinetics: Comparison of Two Methods Based on a Partial-Areas Analysis". *American Association of Pharmaceutical Scientists Annual Meeting*, San Diego, CA, November 13, 2007.
- 178. L. Laksiri, C. Dahyot-Fizelier, S. Lefeuvre, S. Marchand, O. Mimoz, R. J. Sawchuk, and W. Couet. "Microdialysis Study of Imipenem Distribution in the Peritoneal Fluid of Patients with Peritonitis". Interscience Conference on Antimicrobial Agents and Chemotherapy, Washington, DC. October 26, 2008.

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Exhibit E

CV of Dr. Thakker

CURRICULUM VITAE

Dhiren R. Thakker RESIDENCE: 317 Dalton Drive

Raleigh, NC 27615 (919) 870 5126 (Res) (919) 962 0092 (Office) (919) 966 3525 (FAX) Dhiren thakker@unc.edu

PERSONAL: Married, two children, Date of birth: January 25, 1949, Citizen of USA

EDUCATION: Ph.D. (Biochemistry) University of Kansas, Lawrence, KS, 1975

M.S. (Pharmaceutical Chem.) Columbia University, NY, 1972 B.S. (Pharmacy) Bombay University, Bombay, India, 1970

PROFESSIONAL 2/96 - current

EXPERIENCE

Ferguson Distinguished Professor of Pharmaceutical Sciences

Division of Molecular Pharmaceutics (formerly Division of Drug Delivery and

Disposition), School of Pharmacy (now UNC Eshelman School of Pharmacy)

University of North Carolina at Chapel Hill

Chapel Hill, NC 27599

8//08 – current

Associate Dean, Economic Development and International Partnerships UNC Eshelman School of Pharmacy

7/98 - 4/08

Associate Dean, Research and Graduate Education School of Pharmacy (now UNC Eshelman School of Pharmacy)

2/96 - 7/05

Joint appointment: Pharmacology University of North Carolina at Chapel Hill Chapel Hill, NC 27599

12/95 - 2/96

Visiting Professor Pharmaceutics Division, School of Pharmacy University of North Carolina at Chapel Hill, Chapel Hill, NC 27599

3/92 - 11/95

Director, Drug Metabolism Department, Glaxo Research Institute, Research Triangle Park, NC 27709

7/90 - 2/92

Department Head, Drug Metabolism Department, Glaxo Research Institute, Research Triangle Park, NC 27709

12/87 - 7/90

Section Head, Bioorganic Mechanisms Section, Drug Metabolism Department, Glaxo Inc., Research Triangle Park, NC 27709

6/93 - 2/96

Adjunct Professor, Department of Pharmacology, School of Medicine, University of North Carolina, Chapel Hill, NC 27514

11/90 - 2/96

Adjunct Professor, Department of Medicinal Chemistry, School of Pharmacy, University of North Carolina, Chapel Hill, NC 27514

1/84 - 12/87

Senior Investigator, Laboratory of Molecular Pharmacology, Division of Biochemistry and Biophysics, Center for Drugs and Biologics, Food and Drug Administration, Bethesda, MD 20892.

9/78 - 1/84

Senior Staff Fellow/Research Chemist, Laboratory of Bioorganic Chemistry, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health.

9/76 - 8/78

Staff Fellow, Laboratory of Chemistry, National Institute of Arthritis, Metabolism, and Digestive Diseases, National Institutes of Health.

9/75 - 8/76

Visiting Fellow, Laboratory of Chemistry, National Institute of Arthritis, Metabolism and Digestive Diseases, National Institutes of Health.

MANAGEMENT EXPERIENCE

1. Led and Managed the Preclinical Drug Metabolism Department at Glaxo Research Institute

- The department consisted of a staff of 36 including 19 Senior Scientists with Ph.D. or equivalent experience.
- The annual operating budget was \$6 million, and the capital budget was approximately \$1.5 million.
- The primary responsibility of the department was to conduct non-clinical metabolism, pharmacokinetic and toxicokinetic studies in support of development candidates, and to participate in the discovery and selection of new drug candidates to achieve optimum metabolic and pharmacokinetic profiles.
- The department also had the responsibility to synthesize radioisotope-labeled compounds for the Research and Development Divisions.
- 2. As a member of the Technical Development Team (management team), participated in the coordination of exploratory development programs.

- The Technical Development Team had representation from Toxicology, Drug Metabolism, Pharmaceutics, Analytical Chemistry, Process Chemistry, Clinical Pharmacology, Regulatory Affairs, and Project Planning.
- The Technical Development Team participated in the formulation of strategies for exploratory development (preclinical through phase I/phase II) of drug candidates and was responsible for the implementation of these strategies.
- 3. Interacted with the FDA on the non-clinical ADME issues.
- 4. As a member of the Research Management Committees, participated in the management of Discovery Programs in Cancer, Metabolic Diseases, and Inflammation.

PROFESSIONAL ACTIVITIES:

Co-Editor, Medicinal Research Reviews, 2001-2006

Editorial Board, J. Pharm. Sci., Since 1997.

Advisory Board, Office of Technology Development, UNC-Chapel Hill

Advisory Board, Office of Business and Economic Development, UNC-Chapel Hill

Advisory Board, Carolina Student Biotechnology Network, UNC, Chapel Hill

Editorial Board, Current Drug Metabolism, 1999-2002.

Editorial Board, Drug Metabolism and Disposition, 1994-1997.

Board of Directors and Scientific Advisory Board, Qualyst Inc. since 2001.

Drug Development Advisory Board, Scios Inc. (subsidiary of J & J), 2001-2005.

Science and Technology Advisory Board, Oread Inc., 1997-2000.

Scientific Advisory Board, Navicyte, 1999-2001.

Awards Committee, Society for Biomolecular Screening (SBS), 2003-2006.

AAPS Taskforce on Drug Discovery Interface, 2005

Founding Member of the Steering Committee, RTP Drug Metabolism Discussion Group, 1999-2002.

Member of the External Review Committee

Graduate Program, School of Pharmacy, University of Washington, Seattle, 2001.

Basic Pharmacology Advisory Committee

Pharmaceutical Manufacturers' Association Foundation, 1994-1996.

Special Emphasis Panel, National Institute of General Medical Sciences, NIH, 1996.

Organizer - Short Course on "Designing Safe Drugs - Integration of Disposition Studies in Drug Discovery and Development", Residential School on Medicinal Chemistry, Drew University

Organizer and Chair– Short Course on "Prodrug Design – Enhanced and Targeted Delivery of Therapeutic Agents" at the 7th North American ISSX Meeting, October 1996, Sand Diego, CA.

Chair - Special Symposium on "*Drug Delivery and Prodrug Technologies*" at the 31st ACS Western Regional Meeting held in October 1995.

Chair - Session on "Integration of Preclinical ADME Studies in the Preclinical and Clinical Safety Assessment" at the annual meeting of the Drug Information Association, 1994.

Chair - Session on "Delivery and Disposition of Peptides and Oligonucleotides-Current Status and Future Challenges" at the annual meeting of the International Society for the Study of Xenobiotics held in October 1994.

Special reviewer for Geriatric Review Committee, Institute on Aging, 1985.

Reviewer for Investigational New Drug (IND) applications primarily dealing with Interferons and Monoclonal antibodies, 1984-1987.

Reviewer for several leading journals including Nature, Cancer Research, Journal of American Chemical Society, Molecular Pharmacology, Carcinogenesis, Chemico-Biological Interactions, Analytical Biochemistry, Toxicology and Applied Pharmacology, and Chemical Research in Toxicology, Drug Metabolism and Disposition, Pharmaceutical Research, Journal of Pharmaceutical Sciences, Journal of Experimental Therapeutics.

Served as a consultant to Amgen, Amylin Pharmaceuticals, BASF Bioscience, Du Pont Pharmaceuticals, Glaxo Wellcome, ICAgen, Intercardia, Parke Davis, Proctor & Gamble, Synaptics, Triangle Pharmaceuticals, Trimeris, Wyeth, Pozen, Ontogen, Chiron, Scios, *Medivation, Arete, Virobay, Sanofi-Aventis, USVP venture partners* (*Italicized – consulted during 2007*).

Served as an Expert Witness for Wyeth in Wyeth v. Impax Laboratories, Inc. (deposed – Nov 2007).

HONORS AND AWARDS:

FELLOW, American Association of Pharmaceutical Scientists.

SATO MEMORIAL INTERNATIONAL AWARD presented by the Pharmaceutical Society of Japan in 1987.

PHILLIP NEWMARK AWARD for "Excellence in Biochemical Research" at the University of Kansas in 1974.

DISSERTATION FELLOWSHIP at the University of Kansas in 1975.

GRADUATE HONORS FELLOW at the University of Kansas.

Placed SECOND in Bombay University at the B. Pharm. degree examination.

RESEARCH:

- (1) Mechanisms of drug transport across biological barriers
- (2) Regulation and modulation of tight junctions in biological barriers
- (3) Targeted drug delivery to solid tumors via prodrugs
- (4) Gene therapy: in vivo disposition of genes
- (5) Stereoselectivity of cytochrome P450 isoenzymes
- (6) Metabolic activation of xenobiotics to mutagens and carcinogens

Ph.D.

- (1) Development of specific irreversible inhibitors of the enzyme, COMT, which plays an important role in the metabolism of epinephrine, norepinephrine, dopamine, as well as several catecholic endogenous compounds and xenobiotics.
- (2) Study of relationship between physico-chemical properties of 8-hydroxyquinolines and their COMT inhibitory activity (Hansch approach).
- (3) Affinity chromatography of COMT.
- (4) Chemical modification of functional groups on COMT active-site.

M.S.

Synthesis of imidazole derivatives as potential chymotryptic agents.

FUNDING: Current:

 Interplay between CYP3A Metabolism and P-glycoprotein Efflux During Intestinal Absorption of Dual Substrates Dhiren Thakker, PI 2006-2008 \$199,968 (total cost)

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2. A High Throughput Assay for Cytochrome P450-Mediated Metabolism

Dhiren Thakker, PI

North Carolina Biotechnology Center (CFG grant - \$100,000), Qualyst (\$20,000)

2003-2005

\$120,000 (total costs)

3. Novel Absorption Enhancers

Dhiren Thakker, PI

North Carolina Biotechnology Center (SBRA - \$150,000). Qualyst (\$100,000)

2005-2006

\$250,000 (total costs)

4. NC-Pediatric Pharmacology Research Unit

Ross McKinney (Duke), PI; Ralph Raasch, co-PI; Dhiren Thakker; Director, In Vitro Metabolism and Transporter Core

NICHD, NIH

2004-2008

\$657,000 (total costs)

5. Elucidation of Mechanisms underlying Modulation of CYP3A Metabolism by P-gp Efflux during Intestinal Absorption of Dual Substrates

Dhiren Thakker, PI

PhRMA Foundation – Predoctoral Fellowship to Beverly Mowry

2005-2007

\$40,000

Past:

5. Identification of the Transporter(s) for Hydrophilic Cationic Drugs for Photoaffinity Labeling

Dhiren Thakker, PI

University Research Council

\$4,000, 2002-2003

6. Paracellular Transport of Drugs across Intestinal Epithelium

Dhiren Thakker, PI

Ariad Pharmaceuticals

\$30,000 total cost, 2002-2003

7. Intestinal Transport of Drugs

Dhiren Thakker, PI

Arena Pharmaceuticals

\$30,000 total cost, 2002-2003

8. Development of a High Throughput Assay to Assess Susceptibility of Drug

Candidates to Cytochrome P450 (CYP)-mediated Metabolism

Dhiren Thakker, PI

Bristol Myeres Squibb

\$322,540 total costs, 2001-2003

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9. Intestinal Transport of Cationic Hydrophilic Compounds

Dhiren Thakker, PI

NIH

\$1,255,083 total costs, 2002 – 2006, not funded

10. Regulation of Intestinal Epithelial Tight Junctions by Phospholipase C

Dhiren Thakker, PI

Senior Research Award

Crohn's & Colitis Foundation of America

\$230,000 total costs, 2002-2003, not funded

11. Paracellular Transport across Intestinal Epithelium - Structural Requirements for

Paracellular Transport of Drug Molecules

Dhiren Thakker, PI

Bristol Myeres Squibb

\$70,000 total cost, 2001-2002

12. Dual Radioisotope Labeling of Plasmid DNA

Dhiren Thakker, PI

North Carolina Biotechnology Center

\$55,000, not funded

13. P-Glycoprotein Modulates Opioid Peptide Pharmacodynamics

Gary Pollack, PI, Dhiren Thakker (5% effort)

NIH

\$687,079 total costs, 1999 – 2001, not funded

14. Pharmacological Modulation of the Permeability of the Intestinal Epithelium and

Elucidation of Role Played by Biochemical Barriers

Dhiren Thakker, PI

Parke-Davis

\$31,000/year for 2 years, 1999-2001 (year one funded)

15. Role of P-gp in the Transport of Drugs Across Intestinal Epithelium

Dhiren Thakker, PI

Du Pont Pharmaceuticals Co.

\$25,000/year for 2 years, 1999-2001

16. Modulation of Tight Junctions in the Intestinal Epithelium

Dhiren Thakker, PI

Glaxo Wellcome, Inc.

\$35,000, 1999

17. Optimization of Metabolism and PK Properties

Dhiren Thakker, PI

Glaxo Wellcome, Inc. - Glaxo Wellcome - UNC Drug Discovery Program

\$125,000, 1998

18. Barriers to Oral Drug Delivery

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Glaxo Wellcome, Inc. RTP, NC \$250,000, 1996-1998

 Combinatorial Approach for Optimizing ADME Properties of Drug Candidates Diversity Sciences Center, Duke University Durham, NC \$60,000, 1997/98

20. Combinatorial Approach for Development of Structure-Metabolism Relationships North Carolina Biotechnology Center RTP, NC \$40,000, 1997-1998

STUDENTS AND

FELLOWS: Graduate Students:

- 1. Kiho Lee (MCNP) Ph.D., May 2000
- 2. Hui Ouyang (MCNP) Ph.D., Dec 2001
- 3. Peter Ward (Pharmcology) Ph.D., May 2001
- 4. Matt Troutman (DDD) Ph.D., July 2001
- 5. Gururaj Rao (DDD) Ph.D., May 2003
- 6. Chee Ng (DDD) (Chair, Dissertation Committee and co-advisor), Ph.D., May 2003
- 7. Seongwong Hong (MCNP) -Ph.D., May 2004
- 8. David Bourdet (DDD)- Ph.D., August, 2005
- 9. Stephanie Faucette (Molecular Pharmaceutics) Ph.D., May 2006
- 10. Richard Graham (Molecular Pharmaceutics) Ph.D., May 2006
- 11. Tim Tippin (Molecular Pharmaceutics), Ph.D., Dec 2006
- 12. Beverly Mowrey (Molecular Pharmaceutics), Ph.D. Aug 2007
- 13. Ryan Klein (Molecular Pharmaceutics), Ph.D. Dec 2007
- 14. Xin Ming (Molecular Pharmaceutics), Ph.D. expected Aug 2008
- 15. Will Proctor (Molecular Pharmaceutics) 2nd year
- 16. Matthew Dufek (Molecular Pharmaceutics) 2nd year
- 17. Chester Costales (Molecular Pharmaceutics) 1st year
- 18. Souzan Yanni (U. Leuven, Belgium) 2nd year

Postdoctoral Fellows:

- 1. Dr. Yan Gao (2006- 2008)
- 2. Darkhan Utepbergenov (2005-2007)
- 3. Dr. Lorraine King (2001-1002)
- 4. Dr. Johne Ansede (2001-2003)
- 5. Dr. Dongzhou Liu (1996-1998)
- 6. Dr. Shailesh Desai (1996-1999)
- 7. Dr. Cuiping Chen (1997-1998)
- 8. Dr. Sonia Serron (1997-1998)
- 9. Dr. Pieter Annaert (1998-1999)
- 10. Dr. Ashwin Patel (1998-2000)

Research Assistant Professor:

1. Dr. Steven Qian (2004-2005)

Visiting Scientist:

- 1. Souzan Yanni
- 2. Dr. Harish Padh, Director, PERD Center, Ahmadabad, India (June September 2006)

DISSERTATION

COMMITTEES:

- 1. Cuiping Chen, DDD (Ph.D. 1997)
- 2. Catherine Booth, DDD (Ph.D. 1997)
- 3. Xinrong Liu, DDD (Ph.D. 1998)
- 4. Mark Bush, DDD (Ph.D. 1999)
- 5. Kay Rittenhaus, DDD (Ph.D. 1999)
- 6. James Whisnant, DDD (M.S. 1999)
- 7. Mark Summerville, DDD (Ph.D. 2000)
- 8. Jennifer(Quin) Dong, DDD (Ph.D. 2000)
- 9. Claude Degenais, DDD (Ph.D. 2001)
- 10 Preethi Krishnan, MCNP (Ph.D. 2001)
- 11. Christopher Lowden, MCNP (Ph.D. 2001)
- 12. Jessica Smith, DDD (Ph.D., 2001)
- 13. Jian Zong, DDD (Ph.D., 2002)
- 14. Ryan Turncliff, DDD (Ph.D. 2004)
- 15. Chris Matheny, DDD (Ph.D. 2003)
- 16. Lian Zhou, MCNP (Ph.D., 2002)
- 17. Carolyne Cyne (Pharmacology Ph.D. committee)
- 18. Peter Sazani, Pharmacology (Ph.D., 2002)
- 19. Craig Lee, Exp. Therapeutics (Chair) (Ph.D., 2006)
- 20. Scott Barrow, Toxicology Curriculum (Ph.D., 2004)
- 21. Enzo Palma Molecular Pharmaceutics (Ph.D. 2006)
- 22. Dongmei Liu, Molecular Pharmaceutics (Chair) (Ph.D. expected in 2007)
- 23. Jian Jiang, Curriculum in Applied and Material Sciences (Ph.D. expected in 2007)
- 24. Xihong Xu, Chemistry, Duke University (Ph.D. 2008)

PUBLICATIONS:

Co-author of 145 publications which include papers in the peer reviewed journals, review articles and book chapters (List Attached), co-editors of 2 books, and co-inventor on 6 patents (issued and pending).

AFFILIATIONS:

- (1) American Chemical Society (ACS)
- (2) American Association for Advancement of Science (AAAS)
- (3) American Society of Pharmacology and Experimental Therapeutics (ASPET)
- (4) American Association for Cancer Research (AACR)
- (5) American Association of Pharmaceutical Scientists (AAPS)
- (6) International Society for the Study of Xenobiotics (ISSX)
- (7) Indian Association for Cancer Research

Thakker CV, November 2008

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PUBLICATIONS

- **1.** Borchardt, R.T. and Thakker, D.: Affinity Labeling of Catechol-O-Methyltransferase with N-Iodoacetyl-3,5-dimethoxy-4-hydroxyphenylethylamine. <u>Biochem. Biophys. Res. Commun.</u>, <u>54</u>: 1233-1239, 1973.
- **2.** Borchardt, R.T. and Thakker, D.R.: Catechol-O-methyltransferase. 6. Affinity Labeling with N-Iodoacetyl-3,5-dimethoxy-4-hydroxyphenylalkylamines. <u>J. Med. Chem.</u>, <u>18</u>: 152-158, 1975.
- 3. Borchardt, R.T. and Thakker, D.R.: Affinity Labeling of Catechol-O-methyltransferase by N-Halonacetyl Derivatives of 3,5-Dimethoxy-4-hydroxyphenylethylamine and 3,4-Dimethoxy-5-hydroxyphylethylamine. Kinetics of Inactivation. Biochemistry, 14: 4543-4551, 1975.
- **4.** Borchardt, R.T., Cheng, C.G. and Thakker, D.R.: Purification of Catechol-O-methyltransferase. 8. Structure-Activity Relationships for Inhibition by 8-Hydroxyquinolines. <u>J. Med. Chem.</u>, <u>63</u>: 69-77, 1975.
- **5.** Bochardt, R.T., Thakker, D.R., Warner, V.D., Mirth, D.B. and Sane, J.M.: Catechol-O-methyltransferase. 8.Structure-Activity Relationships for Inhibition by 8-Hythyltransferase. <u>J. Med. Chem.</u>, 19: 558-560, 1976.
- 6. Brochardt, R.T. Reid, J. R., Thakker, D.R., Liang, Y.O., Wightman, R.W. and Adams, R.N.: Catechol-O-methyltransferase. 9. Mechanisms of Inactivation by 6-Hydroxydopamine. <u>J. Med. Chem.</u>, <u>19</u>: 1201-1209, 1976.
- 7. Borchardt, R.T. and Thakker, D.R.: Evidence for Sulfhydryl Groups at the Active Site of Catechol-O-methyltransferase. <u>Biochim. Biophys. Acta</u>, <u>445</u>: 598-609, 1976.
- 8. Borchardt, R.T. and Thakker, D.R.: Affinity Labeling of Catechol-O-Methyltransferase using N-Haloacetyl Derivatives of 3,5-Dimethoxy-4-hydroxyphenylethylamine and 3,4-Dimethoxy-5-hydroxyphenylethylamine. In Jacoby, W.B. and Wilchek, M. (Ed.): Methods in Enzymology Affinity Labeling. New York, Academic Press, 1977, Vol. 46, pp. 554-561.
- **9.** Lu, A.Y.H., Levin, W., Vore, M. Conney, A.H., Thakker, D.R., Holder, G. and Jerina, D.M.: Metabolism of Benzo[a]pyrene by Purified Liver Microsomal Cytochrome P-448 and Epoxide Hydrase. In Freudenthal, R.I. and Jones, P.W. (Ed.): Polynuclear Aromatic Hydrocarbons: Chemistry, Metabolism, and Carcinogenesis. New York, Raven Press, 1976, Vol. 1, pp. 115-126.
- 10. Thakker, D.R., Yagi, H., Lu, A.Y.H., Levin, W., Conney, A.H. and Jerina, D.M.: Metabolism of Benzo[a]pyrene IV. Conversion of (+)-Trans-7,8-dihydroxy-7,8-dihydrobenzo[a]pyrene to the Highly Mutagenic 7,8-Diol-9,10-epoxides, Proc. Natl. Acad. Sci. USA, 73: 3381-3385, 1976.
- 11. Thakker, D.R., Yagi, H., Akagi, H., Koreeda, M., Lu, A.Y.H., Levin, W., Wood, A. W., Conney, A.M.: Metabolism of Benzo[a]pyrene VI. Stereoselective Metabolism of Benzo[a]pyrene and Benzo[a]pyrene 7,8-Dihydrodiol to Diol Epoxides. Chem.-Biol. Interact., 16: 281-300, 1977.
- **12.** Thakker, D.R., Yagi, H., Levin, W., Lu, A.Y.H., Conney, A.H. and Jerina, D.M.: Stereospecificity of Microsomal and Purified Epoxide Hydrase from Rat Liver: Hydration of Arene Oxides of Polycyclic Hydrocarbons. <u>J. Biol.</u> Chem., 252: 6328-6334, 1977.
- Yagi, H., Thakker, D.R. Hernandex, O., Koreeda, M. and Jerina, D.M.: Synthesis and Reactions of the Highly Mutagenic 7,8-Diol-9,10-epoxides of the Carcinogen Benzo[a]pyrene. J. Am. Chem. Soc., 99: 1604-1611, 1977.

- Yagi, H., Thakker, D.R., Mah, H.D., Koreeda, M. and Jerina, D.M.: Absolute Stereochemistry of the Highly Mutagenic 7,8-Diol-9,10-epoxides Derived from the Potent Carcinogen trans-7,8-Dihyroxy-7,8-dihydrobenzo[a]pyrene. J. Am. Chem. Soc., 99: 2358-2359, 1977.
- Whalen, D.L. Montemarano, J.A., Thakker, D.R., Yagi, H. and Jerina, D.M.: Changes of Mechanism and Product Distributions in the Hydrolysis of benzo[a]pyrene 7,8-Diol-9,10-epoxide metabolites Induced by Changes in pH. <u>J. Am. Chem. Soc.</u>, <u>99</u>: 5522-5524, 1977.
- **16.** Wood, A.W., Chang, R.L., Levin, W., Yagi, H. Thakker, D.R., Jerina, D.M., and Conney, A.H.: Differences in Mutagenicity of the Optical Enantiomers of the Diastereomeric Benzo[a]pyrene 7,8-Diol-9,10-epoxides. <u>Biochem. Biophys. Res. Commun.</u>, 77: 1389-1396, 1977.
- **17.** Wood, A.W., Levin, W., Ryan, D., Thomas, P.E., Yagi, H., Mah, H.D., Thakker, D.R., Jerina, D.M., and Conney, A.H.: High Mutagenicity of Metabolically Activated Chrysene 1,2-Dihydrodiol: Evidence for Bay Region Activation of chrysene. Biochem. Biophys. Res. Commun., 78: 847-854. 1977.
- 18. Levin, W., Wood, A.W., Lu, A.Y.H., Ryan, D., West, S., Thakker, D.R., Yagi, H., Jerina, D.M., and Conney, A.H.: Role of Purified Cytochrome P-448 and Epoxide Hydrase in the Activation and Detoxification of Benzo[a]pyrene. In Jerina, D.M. (Ed.): <u>Drug Metabolism Concepts.</u> Washington, D.C., American Chemical Society, 1977, ACS Symposium Series 44, pp. 99-126.
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- 2. PLC-based Absorption Enhancers, patent pending
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INVITED LECTURES

- 1. Clinical Society of Washington, Rockville, MD., 1976.
- 2. Department of Pharmacology, George Washington University, Washington, D.C., 1977.
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- 5. Departments of Medicinal Chemistry and Biochemistry, University of Kansas, Lawrence, KS, 1978.
- 6. Environmental Health Chemistry Symposium, American Chemical Society, Washington, DC., 1979.
- 7. 39th International Congress of Pharmaceutical Sciences, Brighton, U.K., 1979.
- 8. Department of Chemical Technology, Bombay University, Bombay, India, 1980.
- 9. Cancer Research Institute, Bombay, India, 1980.
- 10. Bristol Myers Laboratories, Syracuse, NY., 1980.
- **11.** Laboratory of Developmental Pharmacology, National Institute of Child Health and Human Development, NIH, Bethesda, MD., 1981.
- 12. Laboratory of Biochemistry and Metabolism, NIADDK, NIH, Bethesda, MD., 1981.
- 13. International Symposium on Biological Reactive Intermediates, Gilford, Surrey, U.K., 1981.
- 14. Interx-Merck Pharmaceutical Co., Lawrence, KS., 1982.
- 15. Smith Kline Beckman, Philadelphia, PA., 1982.
- 16. Indian Pharmaceutical Association, Bombay, India, 1983.
- 17. Cancer Research Institute, Bombay, India, 1983.
- **18.** National Center for Drugs and Biologics, FDA, Bethesda, MD., 1983.
- 19. Department of Pharmaceutical Chemistry, University of Kansas, Lawrence, KS., 1984.
- 20. Smith Kline Beckman, Philadelphia, PA., 1985.
- 21. Cancer Research Institute, Bombay, India, 1986.
- 22. Central Drug Research Institute, Lucknow, India, 1986.
- 23. Bhabha Atomic Research Center, Bombay, India, 1986.
- 24. Hochest Pharmaceuticals, Bombay, India, 1986.
- **25.** 6th International Catecholamine Symposium, Jerusalem, Israel, 1987.

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- **26.** SATO Memorial International Award Lecture at the 107th Annual Meeting of the Pharmaceutical Society of Japan, Kyoto, Japan, 1987.
- 27. Nagoya City University, Facility of Pharmaceutical Sciences, Nagoya, Japan, 1987.
- 28. Tohuku University, Research Institute for Tuberculosis and Cancer Sendai, Japan, 1987.
- 29. Keio University School of Medicine Tokyo, Japan, 1987.
- **30.** Tokyo College of Pharmacy, Tokyo, Japan, 1987.
- **31.** National Institute of Hygienic Sciences, Tokyo, Japan, 1987.
- 32. Department of Chemical Technology, Bombay University, Bombay, India, 1987.
- 33. Laboratory of Bioorganic Chemistry, NIDDk, Bethesda, MD., 1987.
- **34.** Carcinogen Risk Assessment, Banbury Center, Cold Spring Harbar, 1987.
- 35. Pharmaceutical Institute, School of Medicine, Keio University, Tokyo, Japan, 1988.
- 36. Tokyo College of Pharmacy, Tokyo, Japan, 1988.
- 37. Dept. of Pharmaceutical Sciences, Nagoya City University, Nagoya, Japan, 1988
- 38. Dept. of Medicinal Chemistry, University of North Carolina, 1989.
- **39.** Dept. of Medicinal Chemistry, University of North Carolina, 1990 (presented 3 lectures in a Course on Drug Metabolism).
- **40.** Dept. of Medicinal Chemistry, University of North Carolina, 1991 (presented 3 lectures in a Course on Drug Metabolism).
- **41.** Dept. of Pharmacology, University of North Carolina, 1991.
- **42.** Annual Meeting of the PMA Drug Metabolism Section, New Orleans, 1991.
- **43.** 25th Annual Higuchi Symposium, Lake of the Ozarks, 1992.
- 44. Enz Lecture, Dept. of Pharmaceutical Chem., University of Kansas, 1992
- **45.** Dept. of Medicinal Chemistry, University of North Carolina, 1992 (presented 3 lectures in a course on Drug Metabolism).
- **46.** Dept. of Medicinal Chemistry, University of North Carolina, 1993 (presented 3 lectures in a course on Drug Metabolism).
- 47. Dept. of Chemistry, Catholic University, Washington, D.C., 1993.
- **48.** Lab of Bioorganic Chemistry, NIDDK, NIH, 1993.
- **49.** Chaired a session on the "Integration of Preclinical ADME studies in the Preclinical and Clinical Safety Assessment" at the National Meeting of Drug Information Association, at Wahington, D.C., 1994.

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- **50.** Chaired a session on "Delivery and Disposition of Peptides and Oligonucleotides- Current Status and Future Challenges" at the annual meeting of the International Society for the Study of Xenobiotics (ISSX), Raleigh, NC, October 1994.
- **51.** Chaired a Special Symposium on "Drug Delivery and Prodrug Technologies" at the 31st ACS Western Regional Meeting, San Diego, CA, October 1995.
- **52.** Conference on "Lead Generation and Optimization", Princeton, NJ, September, 1996.
- **53.** Organized a short course presented a talk on Prodrugs at the 7th North American ISSX Meeting, San Diego, October 1996.
- **54.** Winter Conference on "Medicinal and Bioorganic Chemistry", Steamboat Springs, Colorado, January, 1997.
- **55.** Third International Symposium on Innovations in Pharmaceutical Sciences and Technology", Ahmadabad, India, February 1997.
- **56.** S.N.D.T. College of Pharmacy, Bombay University, Bombay, India, February, 1997.
- **57.** Tata Institute for Cancer Research, Bombay, India, February, 1997.
- 58. Amylin Pharmaceuticals, San Diego, CA, April, 1997
- **59.** Merck Research, West Point, PA, April, 1997.
- 60. Proctor & Gamble, Cincinnatti, OH, June, 1997.
- **61.** AAPS Southeast Regional Meeting, Research Triangle Park, NC, June, 1997.
- **62.** Drew University, (faculty), Princeton, NJ, July, 1997.
- 63. DuPont Merck, Newark, DE, July 1997.
- **64.** Formulations and Drug Delivery, ACS Conference, San Diego, CA, October 1997.
- **65.** Glaxo wellcome, Inc. Pharmaceutics Division, RTP, NC, January, 1998.
- 66. Swiss Chemical Society Minisymposium on Oral Drug Delivery, Basel Switzerland, May, 1998.
- 67. University of Leuven, Workshop on Industry Academic Collaborations, Leuven, Belgium, May 1998.
- 68. Glaxo Wellcome, Inc., Biomet Division, Ware, U.K., May, 1998.
- **69.** AAPS Western Regional Meeting, San Francisco, CA, May, 1998.
- **70.** AAPS Southeastern Regional Meeting, RTP, NC, June, 1998.
- **71.** 28th Annual Gordon Research Conference on Drug Metabolism, Plymouth, NH, July, 1998.
- 72. Drew University, (faculty), Princeton, NJ, July, 1998.
- 73. Pfizer, Inc., Groton, CT, July, 1998.

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- 74, Bristol-Meyer Squibb, Inc., Wallingford, CT, July, 1998.
- 75. School of Pharmacy, University of Michigan, Ann Arbor, MI, September, 1998.
- 76. Higuchi Research Seminar, Lake of Ozarks, MO, March, 1999.
- 77. Glaxo Wellcome, Pharmaceutics Dept., RTP, NC, March, 1999.
- **78.** BASF, Boston, MA, June, 1999.
- 79. Parke Davis, Inc., Ann Arbor, MI, July, 1999.
- **80.** Novartis, East Hanover, NJ, September, 1999.
- **81.** Institute for Innovative Research, (faculty), San Diego, CA, December, 1999.
- 82. Agouron Pharmaceuticals, San Diego, CA, December 1999.
- **83.** Glaxo Wellcome (Pharmaceutics), RTP, NC, March 2000.
- 84. Laboratory of Biorganic Chemistry, NIDDK, NIH, Bethesda, MD, May 2000
- 85. Pratt Fellowship Program, NIH, Bethesda, MD, May 2000
- **86.** Wyeth-Ayerst, Pearl River, N.Y., June 2000
- 87. Drew University (faculty), Princeton, NJ, June 2000
- 88. Chiron, CA, 2001.
- 89. Roche, Palo Alto, CA, 2001
- 90. Guilford Pharmaceuticals, Baltimore, MD, 2001
- 91. Drew University (faculty), Princeton, NJ, 2001
- 92. Drew University (faculty), Course Organizer, priceton, NJ, 2001
- 93. Transform Pharmaceuticals, Boston, MA, 2001
- 94. Bristol-Myers Squibb, Princeton, NJ, 2001
- 95. Albany Biolomolecules, Albany, NY, 2001
- 96. Lilly Pharmaceuticals, Indianapolis, IN, 2001
- 97. 3-D Pharmaceuticals, Philadelphia, PA, 2001
- **98.** Pfizer, Ann Arbor, MI, 2002
- 99. Gilford Pharmaceuticals, Baltimore, MD, 2002

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- 100. Pfizer (Agouron), San Diego, CA, 2002
- 101. Serono Pharmaceuticals, Soreno, Switzerland, 2002
- 102. Avantis, Frankfurt, Germany, 2002
- 103. Bristol Myers Sqibb, Lawrenceville, NJ, 2002
- 104. Avantis, Pearl River, NJ, 2002
- 105. Roche, Nutley, NJ, 2002
- **106.** Pfizer, Groton, CT, 2002
- **107.** GPEN, Detriot, MI, 2002
- 108. GlaxoSmithKline, Philadelphia, PA, 2002
- 109. Arena Pharmaceuticals, San Diego, CA, 2002
- 110. Drew University, Newark, NJ, 2003
- **111.** Novartis, Jolla CA, 2003
- 112. AstraZeneca, Boston, MA, 2003
- 113. Fibrogen, San Francisco, CA 2003
- **114.** ADMET-1, San Diego, CA 2004
- 115. AstraZeneca, San Diego, CA 2004
- 116. LabFusion, Boston, Ma 2004
- **117.** Millennium, Cambridge, MA 2004
- 118. Schering-Plough, Kenilworth, NJ 2004
- 119. Neurocrine, San Diego, CA 2004
- 120. Abbott, Abbott Park, IL 2004
- **121.** Pfizer, Groton, CT, 2005
- 122. ICOS, Bothell, WA, 2005
- 123. SCIOS, Inc. San Francisco, CA, 2005
- **124.** Biogen, Cambridge, MA 2005
- **125.** Genzyme, Framingham, MA 2005

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- **126.** Sunesis, San Francisco, CA 2005
- 127. Drew University, Newark, NJ 2005
- **128.** Amgen, Boston, MA, 2005 "Probing the Intestinal Epithelial Barrier: A Tortuous Journey"
- **129.** Pediatric Pharmacology Research Unit Network Meeting, Washington, D. C., 2005 "Implementing In Vitro Drug Disposition Studies to Improve Pediatric Therapy Challenges and Opportunities"
- **130.** Cambridge Healthcare Institute Mastering Medicinal Chemistry/ADME In-depth, San Francisco, CA, 2006 "ADME In-depth: A Medicinal Chemistry Perspective" (Lead Lecture)
- **131.** Scitech Center, Mumbai, India, 2006 "Integration of ADME in Drug Discovery: Past, Present, and Future"
- **132.** Indian Drug Manufacturers' Association Meeting Bioavailability and Bioequivalence, Mumbai, India, 2006. "Integration of ADME in Drug Discovery: Past, Present, and Future"
- **133.** PERD Center, Ahmedabad, India, 2006 "Integration of ADME in Drug Discovery: Past, Present, and Future"
 - "Probing the Intestinal Epithelial Barrier: A Tortuous Journey"
- 134. Drew University, Madison, NJ, 2006.

"Use of Preclinical Pharmacokinetics and In Vitro Models to Assess Problems of Poor Oral Bioavailability" (with Kim Brouwer)

"Role of Intestinal and Hepatic Metabolism in Drug Clearance – Chemical Strategies to Optimize Metabolic Clearnce"

135. Genentech, San Francisco, CA, 2006.

"Use of Preclinical Pharmacokinetics and In Vitro Models to Assess Problems of Poor Oral Bioavailability" (with Kim Brouwer)

"Role of Intestinal and Hepatic Metabolism in Drug Clearance – Chemical Strategies to Optimize Metabolic Clearnce"

- **136.** New Jersey Drug Metabolism Discussion Group, Newark, NJ, 2006. Intestinal Drug Transport: A Black Box or a Target for Rational Design of Orally Active Drugs?
- **137.** Bristol Myers Squibb, NJ, 2006. Interplay of Transport and Metabolism in the Intestinal Epithelium
- 138. Nektar Pharmaceuticals, Mobile, Alabama/San Diego, CA, 2007
 "Use of Praclinical Pharmacekinetics and In Vitro Models to Assess Problems of

"Use of Preclinical Pharmacokinetics and In Vitro Models to Assess Problems of Poor Oral Bioavailability" (with Kim Brouwer)

"Role of Intestinal and Hepatic Metabolism in Drug Clearance – Chemical Strategies to Optimize Metabolic Clearnce"

139. Molecular Medicine Tri-Conference – ADMET short course, San Francisco, CA, February, 2007. Lead Speaker - *In Vitro* ADME Assays: Strategic Application to Drug Discovery

Thakker CV, November 2008

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- **140.** New England Drug Metabolism Discussion Group Symposium, Boston, MA, April 2007 "Drug Metabolism-Pharmacokinetics-guided (DM/PK-guided) Lead Optimization: A Historical Perspective of a Paradigm Shift"
- **141.** Bayer Pharmaceuticals, Dusseldorf, Germany, January 2008 "Use of Preclinical Pharmacokinetics and In Vitro Models to Assess Problems of Poor Oral Bioavailability" (with Kim Brouwer)
 - "Role of Intestinal and Hepatic Metabolism in Drug Clearance Chemical Strategies to Optimize Metabolic Clearnce"
- **141.** Molecular Medicine Tri-Conference ADMET short course, San Francisco, CA, March, 2008. Lead Speaker "*In Vitro* ADME Assays: Strategic Application to Drug Discovery"

Exhibit F

CV of Dr. Thisted

Ronald A. Thisted

June. 2009

Department of Health Studies

The University of Chicago

5841 South Maryland Avenue (MC 2007)

Chicago, Illinois 60637

Department of Statistics

The University of Chicago

5734 University Avenue

Chicago, Ill 60637

(773) 834-1242

email: thisted@health.bsd.uchicago.edu http://health.bsd.uchicago.edu/thisted/

Education: Ph.D. (Statistics) Stanford University, 1977.

M.S. (Statistics) Stanford University, 1973.

B.A. (Mathematics, Philosophy) Pomona College, 1972. Magna cum laude

Professional: All at the University of Chicago:

2005 – Member, Center for Cognitive and Social Neuroscience

2001–2008 Member, Institute for Mind and Biology

2000 — Director, Biostatistics Core Facility, University of Chicago Cancer Research Center

1999 — Chairman, Department of Health Studies 1999 — Co-Director, Clinical Research Training Program

1996– Professor, Department of Health Studies

1993–1998 Co-Director, Robert Wood Johnson Clinical Scholars Program

1993 – Professor, Committee on Clinical Pharmacology and Pharmacogenomics

1992 — Professor, Departments of Statistics, Anesthesia & Critical Care,

and the College

1989–1992 Associate Professor, Department of Anesthesia and Critical Care 1982–1992 Associate Professor, Department of Statistics and the College

1979–1982 Leonard Jimmie Savage Assistant Professor, Department of Statistics and the College

1976–1982 Assistant Professor, Department of Statistics and the College

Honors: Phi Beta Kappa, Pomona College, 1972.

National Science Foundation Graduate Fellow, 1973–1976.

Sigma Xi, The University of Chicago, 1977.

The Llewellyn John and Harriet Manchester Quantrell Award for Excellence in Undergraduate Teaching, 1981.

Faculty, National Center for Advanced Medical Education, 1990–1992.

Professional Societies:

American Association for the Advancement of Science (Elected Fellow, 1992)

1994–1997 Electorate Nominating Committee, Section on Statistics

American Statistical Association (Elected Fellow, 1988)

1987–1989 Section on Statistical Graphics, Chair (1988)

1994–1996 Executive Committee, Section on Statistical Education

1994–1996 Section Representative, Section on Statistical Computing

American Public Health Association Association for Computing Machinery

Biometric Society

Institute of Mathematical Statistics 1987–1990 Nominating Committee

1989–1993, 1999–2002 Management Committee, Current Index to Statistics

Editorial: Computing Reviews, Reviewer (1978–1987).

J American Statistical Assoc, Associate Editor (1979–1985, 1987–1988).

SIAM J Scientific and Statistical Computing, Editorial Board (1983–1985).

ACM Trans on Math Software, Associate Editor (1990–1992).

Current Index to Statistics, Database Ed. (1994); Managing Ed. (1995); Editor (1996–1998).

Selected Publications

Books

[1] Elements of Statistical Computing: Numerical Computation. Chapman & Hall: London. 1988.

Original Articles

- [2] "The Prediction of Homicide with the Rorschach" (D Lester, J Kendra, R Thisted, W Perdue). J. Clinical Psych., 31, (1976), 752.
- [3] "Estimating the Number of Unseen Species: How Many Words Did Shakespeare Know?" (B Efron, RA Thisted). Biometrika, 63, (1976), 435-447.
- [4] Ridge Regression, Minimax Estimation, and Empirical Bayes Methods. Ph.D. Thesis, Department of Statistics, Stanford University (1976).
- [5] "Prediction of Homicide and Suicide: A Test in a Healthy Risk-Taking Group" (D Lester, JM Kendra, RA Thisted). Perceptual and Motor Skills, 44, (1977), 222.
- [6] "Teaching Statistical Computing Using Computer Packages" (with Discussion), The American Statistician, 33, (1979), 27–35.
- [7] "User Documentation and Control Language I: Evaluation and Comparison of Statistical Computer Packages." Computers & Education, 3, (1979), 135–141.
- [8] "Predicting a Multitude of Time Series" (RA Thisted, WE Wecker). Journal of the American Statistical Association, 75, (1980), 81–86.
- [9] "Lactic Acidemia in Reye's Syndrome" (JH Tonsgard, PR Huttenlocher, RA Thisted). Pediatrics, 69, (1982), 64–69.
- [10] "Maximum Likelihood Estimation of Isotonic Modal Regression" (T Sager, R Thisted). Annals of Statistics, 10, (1982), 690–707.
- [11] "Safety and Efficacy of Chymopapain (Chymodiactin) in Herniated Nucleus Pulposus With Sciatica: Results of a Randomized, Double-blind Study" (MJ Javid, EJ Nordby, LT Ford, WJ Hejna, WW Whisler, C Burton, DK Millett, LL Wiltse, EH Widell Jr, RJ Boyd, StE Newton, RA Thisted). Journal of the American Medical Association, 249:18, (1983), 2489–2494.
- [12] "A Statistical Study of Mate Choice: Sexual Selection in a Plethodontid Salamander (Desmognathus Ochrophæus)," (L Houck, SJ Arnold, RA Thisted). Evolution, 39, (1985), 370–386.
- [13] "Chymodiactin in Patients with Herniated Lumbar Intervertebral Disc(s): An Open-Label, Multicenter Study," (DJ McDermott, K Agre, M Brim, FJ Demma, J Nelson, RR Wilson, RA Thisted). Spine, 10, (1985), 242–249.
- [14] "Decreased Incidence and Mortality of Anaphylaxis to Chymopapain," (J Moss, MF Roizen, EJ Nordby, RA Thisted, JL Apfelbaum, BD Schreider, DJ McDermott). Anesthesia and Analgesia, 64, (1985), 1197–1201.
- [15] "Computing Environments for Data Analysis," (with Discussion), Statistical Science, 1, (1986), 259–275.
- [16] "Did Shakespeare Write a Newly-Discovered Poem?" (R Thisted, B Efron). Biometrika, 74, (1987), 445–455.
- [17] "Cervical Injury in Head Trauma," (GL Neifeld, JG Keene, G Hevesy, J Leikin, A Proust, RA Thisted). Journal of Emergency Medicine, 6, (1988), 203–207.
- [18] "Patient-Applied Podofilox for Treatment of Genital Warts," (KR Beutner, MA Conant, AE Friedman-Kien, M Illeman, NN Artman, RA Thisted, DH King). Lancet, (1989, April 15), 831–834.
- [19] "Using a National Health Care Data Base to Determine Surgical Complications in Community Hospitals: Lumbar Discectomy as an Example" (L Ramirez, R Thisted). Neurosurgery, 25, (1989), 218–225.
- [20] "Complications and Demographic Characteristics of Patients Undergoing Lumbar Discectomy in Community Hospitals," (L Ramirez, R Thisted). Neurosurgery, 25, (1989), 226–231.

- [21] "Increased Risk for Gestational Diabetes Mellitus Associated with Insulin Receptor and Insulinlike Growth Factor II Restriction Fragment Length Polymorphisms" (C Ober, KS Xiang, RA Thisted, KA Intovina, CJ Wason, S Dooley). Genetic Epidemiology, 6, (1989), 559–569.
- [22] "Alcohol after Midazolam Sedation: Does it Really Matter?," (JL Lichtor, J Zacny, K Korttila, JL Apfelbaum, BS Lane, G Rupani, RA Thisted, C Dohrn), Anesthesia & Analgesia, 72, (1991), 661–666.
- [23] "Spreading Depression Increases Immunohistochemical Staining of Glial Fibrillary Acidic Protein," (RP Kraig, L Dong, R Thisted, CB Jaeger). Journal of Neuroscience, 11(7), (1991), 2187–2198.
- [24] "Intravenous Lidocaine does not Cause Shivering-like Tremor or Alter Thermoregulation," (B Glosten, DI Sessler, LG Östman, EAM Faure, L Karl, RA Thisted). Regional Anesthesia, 16, (1991), 218–222.
- [25] "The Automated Interview vs. the Personal Interview: Do Patient Responses to Preoperative Health Questions Differ?" (RE Lutner, MF Roizen, CB Stocking, RA Thisted, S Kim, PC Duke, P Pompeii, CK Cassel). Anesthesiology, 75, (1991), 394–400.
- [26] "Predictors of Body Surface Area" (Y Wang, J Moss, R Thisted). Journal of Clinical Anesthesia, 4, (1992), 4–10.
- [27] "Alcohol After Intravenous Midazolam-Fentanyl Sedation: Effects on Psychomotor Functioning," (JL Lichtor, J Zacny, JL Apfelbaum, BS Lane, G Rupani, RA Thisted, C Dohrn, K Kortilla). British Journal of Anesthesia, 67, (1991) 579–584.
- [28] "Sleep and Psychiatric Disorders: A Meta-Analysis," (RM Benca, WH Obermeyer, RA Thisted, JC Gillin). Archives of General Psychiatry, 49, (1992), 651–668. With editorial.
- [29] "Thromboelastogram Fails to Predict Postoperative Hemorrhage in Cardiac Patients," (JS Wang, CY Lin, WT Hung, MF O'Connor, RA Thisted, BK Lee, RB Karp, MW Yang). Annals of Thoracic Surgery, 53, (1992), 435–439.
- [31] "Central Temperature Changes are not Perceived During Epidural Anesthesia," (B Glosten, DI Sessler, EAM Faure, L Karl, RA Thisted). Anesthesiology, 77, (1992), 10–16.
- [32] "The Risk of Human Immunodeficiency Virus in Surgeons, Anesthetists, and Medical Students," (JM Buergler, R Kim, RA Thisted, MF Roizen). Anesthesia & Analgesia, 75, (1992), 118–124.
- [33] "Reassessment of Preoperative Laboratory Testing Has Changed the Test-Ordering Patterns of Physicians" (A Macario, MF Roizen, RA Thisted, S Kim, FK Orkin, C Phelps). Surgery, Gynecology & Obstetrics, 175, (1992), 539–547.
- [34] "Echocardiographic Analysis of Dysfunctional and Normal Myocardial Segments Before and Immediately After Coronary Artery Bypass Graft Surgery," (P Voci, F Bilotta, S Aronson, G Scibilia, Q Caretta, C Mercanti, B Marino, R Thisted, MF Roizen, A Reale). Anesthesia & Analgesia, 75, (1992), 213–218.
- [35] "The Influence of Intravenous Albunex Injections on Pulmonary Arterial Pressure, Gas Exchange, and Left Ventricular Peak Intensity," (R Walker, JG Weincek, S Aronson, J Zaroff, D Glock, R Thisted, SB Feinstein). Journal of the American Society of Echocardiography, 5, (1992), 463–470.
- [36] "In Vitro Effects of Aprotinin on Activated Clotting Time Measured with Different Activators," (JS Wang, CY Lin, WT Hung, RA Thisted, RB Karp). Journal of Thoracic and Cardiovascular Surgery, 104, (1992), 1135–1140.
- [37] "Can Patients Use an Automated Questionnaire to Define Their Current Health Status?" (MF Roizen, D Coalson, RS Hayward, J Schmittner, RA Thisted, JL Apfelbaum, CB Stocking, P Pompei, DE Ford, et al). Medical Care, 30, (1992), MS74–84.
- [38] "Disease-Specific Survival Following Routine Prostate Cancer Screening by Digital Rectal Examination," (GS Gerber, IM Thompson, R Thisted, GW Chodak). Journal of the American Medical Association, 269, (1993), 61–64.
- [39] "The Interaction between Alcohol and the Residual Effects of Thiopental," (JL Lichtor, JP Zacny, DW Coalson, DC Flemming, A Uitvlugt, JL Apfelbaum, BS Lane, RA Thisted). Anesthesiology, 79, (1993), 28–35.

- [40] "A proposal to use confidence intervals for visual analog scale data for pain measurement to determine clinical significance," (S Mantha, R Thisted, J Foss, JE Ellis, MF Roizen). Anesthesia & Analgesia, 77, (1993), 1041–1047.
- [41] "The initial clinical experience of 1819 physicians in maintaining anesthesia with propofol: Characteristics associated with prolonged time to awakening," (JL Apfelbaum, TH Grasela, CC Hug, CH McLeskey, ML Nahrwold, MF Roizen, TH Stanley, RA Thisted, CA Walawander, PF White). Anesthesia & Analgesia, 77, (1993), S10–14.
- [42] "The role of pharmacoepidemiology research in postmarketing surveillance and anesthesia practice/critical care medicine," (TH Grasela, WD Watkins, CC Hug, CH McLeskey, ML Nahrwold, MF Roizen, TH Stanley, RA Thisted, CA Walawander, PF White, JL Apfelbaum). Anesthesia & Analgesia, 77, (1993), S44–50.
- [43] "Hemodynamic effects of propofol: Data from over 25,000 patients," (CC Hug, CH McLeskey, ML Nahrwold, MF Roizen, TH Stanley, RA Thisted, CA Walawander, PF White, JL Apfelbaum, TH Grasela). Anesthesia & Analgesia, 77, (1993), S21–29.
- [44] "Adverse events in a multicenter Phase IV study of propofol: Evaluation by anesthesiologists and PACU nurses," (CH McLeskey, CA Walawander, ML Nahrwold, MF Roizen, TH Stanley, RA Thisted, PF White, JL Apfelbaum, TH Grasela, CC Hug). Anesthesia & Analgesia, 77, (1993), S3-9.
- [45] "Phase IV study of propofol: Validation of the data set," (ML Nahrwold, MF Roizen, TH Stanley, RA Thisted, CA Walawander, PF White, JL Apfelbaum, TH Grasela, CC Hug, CH McLeskey). Anesthesia & Analgesia, 77, (1993), S34-43.
- [46] "How do anesthesiologists select patients when introducing a new drug into practice?" (MF Roizen, TH Stanley, RA Thisted, CA Walawander, PF White, JL Apfelbaum, TH Grasela, CC Hug, CH McLeskey, ML Nahrwold). Anesthesia & Analgesia, 77, (1993), S30–33.
- [47] "Effects on recovery when isoflurane is used to supplement propofol-nitrous oxide anesthesia," (PF White, TH Stanley, JL Apfelbaum, TH Grasela, CC Hug, CH McLeskey, ML Nahrwold, MF Roizen, RA Thisted, CA Walawander). Anesthesia & Analgesia, 77, (1993), S15–20.
- [48] "Predictive and Diagnostic Tests of Renal Failure: A Review," (M Kellen, S Aronson, MF Roizen, J Barnard, RA Thisted). Anesthesia & Analgesia, 78, (1994), 134–142.
- [49] "Association of Preoperative Risk Factors with Postoperative Acute Renal Failure," (BK Novis, MF Roizen, S Aronson, RA Thisted). Anesthesia & Analgesia, 78, (1994), 143–149.
- [50] "Results of Conservative Management of Clinically Localized Prostate Cancer," (GW Chodak, RA Thisted, GS Gerber, J-E Johansson, J Adolfsson, G Jones, G Chisholm, B Moskovitz, J Warner). New England Journal of Medicine, 330, (1994), 242–248.
- [51] "Relative Effectiveness of Four Preoperative Tests for Predicting Adverse Cardiac Outcomes After Vascular Surgery: A Meta-Analysis," (S Mantha, MF Roizen, J Barnard, RA Thisted, JE Ellis, J Foss). Anesthesia & Analgesia, 79, (1994), 422–433.
- [52] "Premedication with Oral and Transdermal Clonidine Provides Safe and Efficacious Postoperative Sympatholysis," (JE Ellis, G Drijvers, S Pedlow, SP Laff, MJ Sorrentino, JF Foss, M Shah, JR Busse, S Mantha, J McKinsey, J Osinski, RA Thisted, MF Roizen). Anesthesia & Analgesia, 79, (1994), 1133–40.
- [53] "Mucosal allergy in the absence of systemic allergy in nasal polyposis and rhinitis: a metaanalysis," (JS Shatkin, KG Delsupehe, RA Thisted, JP Corey). Otolaryngology – Head & Neck Surgery, 111(5), (1994), 553–6.
- [54] "Estimation of the association between desipramine and the risk for sudden death in 5 to 14-year-old children," (J Biederman, RA Thisted, L Greenhill, ND Ryan). Journal of Clinical Psychiatry, **56**, (1995), 87–93.
- [55] "A comparison of intraarticular morphine to bupivicaine for pain control following local knee arthroscopy in the day surgery setting: A prospective, randomized, double-blinded study," (JW Jaureguito, JF Wilcox, SJ Cohn, RA Thisted, B Reider). American Journal of Sports Medicine, 23, (1995), 350–3.

- [56] "Prospective, randomized, double-blind trial of BQ-123 and bosentan for prevention of vasospasm following subarachnoid hemorrhage in monkeys." (A Hino, BK Weir, RL Macdonald, RA Thisted, et al) Journal of Neurosurgery, 83, (1995), 503–9.
- [57] "Resolved: cardiac arrhythmias make desipramine an unacceptable choice in children." (JS Werry, J Biederman, R Thisted, L Greenhill, et al) Journal of the American Academy of Child & Adolescent Psychiatry, 34, (1995), 1239–45; discussion 1245–8.
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Selected Grants and Contracts

5K30 HL04093-02 Coe, F. (PI) 6/1/99-9/27/07 (NIH)

Clinical Research Training Program

Roles: Program Co-Director, Seminar Director

UL1 RR024999 Solway, J. (PI) 9/28/07-present (NIH)

Clinical and Translational Science Award

Roles: Population Sciences Cluster Director, Clinical Research Training Program Co-Director

P01 AG18911 Cacioppo, J. (PI) 7/1/01-6/30/06 (NIH)

Social Isolation, Health and the Aging Process; Biostatistical Core B

Role: Director, Biostatistics Core

2 P30 CA14599-28 Le Beau, M. (PI) 4/1/02-present (NIH/NCI)

UCCRC-Cancer Center Support Grant; Subproject: Biostatistics Facility

Role: Scientific Director of Biostatistics, Executive Committee of Cancer Center

U01 DK62429 Cho, J (PI) 9/30/02-present (NIH/NIDDK)

IBD Genetics Consortium Data Coordinating Center

Role: Co-Investigator, Data Management Core

R01 NS40229 Frank (PI) 9/18/99-6/30/03 (NIH)

Hemicraniectomy for Swelling from Cerebral Infarction

Role: Director, Data Coordinating Center

Cassell, C. (PI) 7/1/93–6/30/95

Thisted, R. (PI) 7/1/95-6/30/98

Levinson, W. (PI) 7/1/98-6/30/01

Lantos, J. (PI) 7/1/02–6/30/06 (Robert Wood Johnson Foundation)

Clinical Scholars Program

Role: Co-PI to 1998, Co-Director to 1999; Core-Faculty; Advisory Board

Teaching

Recent Courses

2009 Health Studies 327: Biostatistical Methods

Seminar in Clinical Research Methods (30 weeks)

Medicine 777: Advanced Clinical Pharmacology (Lecture: Pharmacoepidemiology)

Family Medicine 304: Epidemiology and Clinical Investigation (Lecture: Screening Tests)

2008 Health Studies 327: Biostatistical Methods

Seminar in Clinical Research Methods (30 weeks)

Statistics 307/Computer Science 378: Numerical Computation

2007 Health Studies 327: Biostatistical Methods

Seminar in Clinical Research Methods (30 weeks)

Medicine 777: Advanced Clinical Pharmacology (Lecture: Pharmacoepidemiology)

Statistics 307/Computer Science 378: Numerical Computation

2006 Health Studies 327: Biostatistical Methods

Seminar in Clinical Research Methods (30 weeks)

Medicine 777: Advanced Clinical Pharmacology (Lecture: Pharmacoepidemiology)

2005 Statistics 307: Numerical Computation

Seminar in Clinical Research Methods (30 weeks)

2004 Health Studies 327: Biostatistical Methods

Health Studies 541: Epidemiology and Clinical Investigation

(Lecture: Chronic Disease Epidemiology)

Medicine 777: Advanced Clinical Pharmacology (Lecture: Pharmacoepidemiology)

Medicine 603: Critical Appraisal of Medical Literature (Lecture: Statistical issues)

Seminar in Clinical Research Methods (30 weeks)

2003 Health Studies 541: Epidemiology and Clinical Investigation

Health Studies 327: Biostatistical Methods

Medicine 777: Advanced Clinical Pharmacology (Lecture on Pharmacoepidemiology)

Medicine 603: Critical Appraisal of Medical Literature (Lecture: Statistical issues)

Seminar in Clinical Research Methods (30 weeks)

2002 Health Studies 541: Epidemiology and Clinical Investigation

Medicine 777: Advanced Clinical Pharmacology (Lecture on Pharmacoepidemiology)

Medicine 603: Critical Appraisal of Medical Literature (Lecture: Statistical issues)

Seminar in Clinical Research Methods (30 weeks)

2001 Health Studies 541: Epidemiology and Clinical Investigation

Statistics 224: Applied Regression Analysis

Medicine 777: Advanced Clinical Pharmacology (Lecture on Pharmacoepidemiology)

Medicine 603: Critical Appraisal of Medical Literature (Lecture: Statistical issues)

Seminar in Clinical Research Methods (30 weeks)

University Committees

Current appointments:

Executive Committee, Clinical Research Training Program, 1999-.

Executive Committee, Biological Sciences Division, 2000-.

Committee of Basic Science Chairs, Biological Sciences Division, 1999-.

University of Chicago Medical Center, Budget Oversight Committee, 2007-.

Executive Committee, Institute of Translational Medicine (CTSA), 2007-.

Faculty Science Review Committee, 2009-.

Previous appointments (since 1988):

Committee of Clinical Chairs, Biological Sciences Division, 1999–2006.

Executive Committee, University of Chicago Cancer Research Center, 2000–2005.

Advisory Committee, Robert Wood Johnson Clinical Scholars Program, 1999–2006.

Search Committee (Chair), Chairman of Department of Psychiatry, 2003–2004.

Committee to Review Appointments and Promotions, 2003–2004.

Tenure and Tracks Committee, 2003–2004.

Committee to Advise the Provost on Federal Wide Assurance (Chair), 2003.

Research Aims Committee, Division of Biological Sciences, 2002–2003.

Search Committee, Chairman of Department of Obstetrics & Gynecology, 2000–2003.

Faculty Committee to Advise the President on the Dean of the Biological Sciences Division, 2001–2002.

Search Committee, Chairman of Department of Family Medicine, 2000–2002.

Provost's Committee on Medical Informatics, 2000–2001.

Clinical Translational Advisory Group, Biological Sciences Division, 1999–2001.

Co-chair, Committee on Law and Medicine, BSD and Law School, 1999–2000.

Working Group on Clinical Data Sharing, 1999–2001.

Executive Committee, Department of Anesthesia & Critical Care, 1994–1998.

Institutional Review Board, Division of Biological Sciences, 1983–1986, 1987–1997.

Faculty Campus Planning Committee, 1993–1996.

College Curriculum Committee, 1990–1996.

Board of Computing Activities and Services 1981–1986, 1991–1994.

Physical Sciences Division, Space/Facilities Committee, 1992–1994.

Committee on Family Practice (BSD), 1993.

Provost's Committee on Health Studies, 1993.

Health Studies Committee (BSD), 1991-1992.

College Council, 1979–1982, 1983-1986, 1989–1992.

Working Committee on Public Computing, 1987–1988.

Refereeing, 2005-

Annals of Statistics

Regulatory Pharmacology and Toxicology

Journal of Clinical Oncology

Journal of Surgical Research

Neuropsychopharmacology

Perspectives in Biology and Medicine

Statistics in Medicine

NIH, Center for Scientific Review (Surgery, Anesthesiology and Trauma study section)

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NIH, Center for Scientific Review (Challenge Grant Editorial Panel HDM-P) NSF, Division of Mathematical Sciences